

MAVIS

MEDICINES ACT VETERINARY INFORMATION SERVICE

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■ REPEAL OF SECTION 118 OF THE MEDICINES ACT 1968 AND REG 14 OF THE MARKETING AUTHORISATIONS FOR VETERINARY MEDICINAL PRODUCTS REGULATIONS 1994

In December 2002 we held a joint consultation exercise with the Medical and Health Products Regulatory Agency (MHRA) on the future of Section 118 of the Medicines Act 1968 and Regulation 14 of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994. Section 118, in summary, prohibits disclosure of information obtained under provision of the 1968 Act “unless the disclosure was made in the performance of duty”. The VMD and MHRA sought comments on the possible retention, replacement or repeal of Section 118.

The majority of those that replied to the consultation were in favour of the repeal of Section 118 and of those replies over half wanted the relevant provisions of the Freedom of Information Act 2000 to come into force immediately on the repeal of Section 118.

With this weight of support, Ministers have agreed that Section 118 of the Medicines Act will be repealed in January 2005, which will coincide with the full implementation of the Freedom of Information Act. Consideration is currently being given to how to take this forward in practice.

The full implementation of the individual rights of access to information contained in the Freedom of Information Act 2000, comes into force in January 2005. The FOI legislation contains a number of exemptions that allow public bodies to refuse to release information, unless it is clearly in the public interest to do so. These exemptions include safeguards for commercial confidentiality and trade secrets.



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The best available information on the work of the VMD can be found on our on-line MAVIS service www.vmd.gov.uk



INVESTOR IN PEOPLE

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ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

■ INVITATION TO APPLY FOR MEMBERSHIP OF THE VETERINARY RESIDUES COMMITTEE

The Veterinary Residues Committee (VRC) is an independent advisory committee, which plays an important role in the safety of our food.

The Chief Executives of the Veterinary Medicines Directorate and the Food Standards Agency invite applications to fill a number of specialist posts on the VRC with effect from 1 January 2005.

The terms of office of the Chairman and members of the VRC come to an end on 31 December 2004.

We invite applications from anyone who is qualified and has current, relevant experience in:

- a) chairing advisory committees,
- b) consumer issues,
- c) toxicology,
- d) veterinary surgery with experience of farming/animal husbandry, and
- e) retail industry.

Candidates must be good team players, with effective communication, negotiation, judgement and influencing skills combined with strong analytical and problem solving skills. As members they must be able to weigh issues outside their own specialist areas and to appreciate the impact that their decisions may have on public health. They must also be able to work in a committee structure and to arrive at sound, balanced and timely decisions.

Appointments will initially be for a two-year term. There are normally three meetings a year at the Veterinary Medicines Directorate. An attendance allowance and preparation fee will be available and all legitimate expenses supported by receipts will be fully reimbursed.

Selection will be in accordance with the Government's Equal Opportunities policy. Appointments to the VRC are made in accordance with the Code of Practice for Ministerial Appointments to Public Bodies issued by the Office of the Commissioner of Public Appointments (OCPA). The OCPA is also charged with the responsibility for investigating complaints, but these should be addressed, in the first instance, to:

The Chief Executive
Veterinary Medicines Directorate
New Haw
Addlestone
Surrey
KT15 3LS.

If you are interested in applying for membership of the VRC, an information pack and application form may be obtained from:

Colin Bennett
VRC Appointments' Secretary
Veterinary Medicines Directorate
Woodham Lane
New Haw
Surrey
KT15 3LS

Tel: 01932 338490
Fax: 01932 336618
E-mail: c.bennett@vmd.defra.gsi.gov.uk;

The closing date for receipt of completed applications is 23 April 2004.

■ STAFF CHANGES

The following staff changes have taken place since the last issue of *MAVIS*.

- Carol Long left the VMD on 31 October 2003 to take up a position in core Defra. Alex Tait was the successful candidate in the recent exercise to fill Carol's post in the ecotoxicology team.
- Sam Fletcher transferred on promotion to HSO from the Residues team to the Safety team on 24 November 2003.
- Martin Ilott was promoted to head the Immunologicals team on 12 January 2004.
- Fran Brooks has been seconded for a six-month period, as a Programme Office Support Manager to the RDS Programme Manager. Her post as Personal Secretary to Steve Dean will be filled in the interim by Lisa Pritchard. Both postings took effect from 2 February 2004.
- Jo Gough transferred from Suspected Adverse Reactions Surveillance Scheme to work in Human Resources on 5 January 2004
- Carol Brailsford transferred from Information Management to the VPC Secretariat on 5 January 2004.

■ VMD STAKEHOLDERS' MEETING: 18 NOVEMBER 2003 SUMMARY NOTE

Opening Remarks

The Chairman, Brian Morris (independent member of the VMD's Management Board) welcomed those present to the fourth VMD Stakeholder meeting. (A list of those present at the meeting can be found on the VMD website). He welcomed, in particular, the Head of the Latvian Veterinary Service and his colleagues who were attending the meeting to gain a greater understanding of the VMD's role. The Chairman thanked those attending for responding so rapidly to the change of location for this meeting.

The Chairman invited Verner Wheelock of Verner Wheelock Associates to make a statement relating to the comment made by the British Veterinary Association (BVA) at the Stakeholder meeting on 28 January that the BVA had asserted that, in Denmark, where the linkage between the veterinarian prescribing and selling antibiotics had been broken, therapeutic usage had increased. Mr Wheelock considered that this statement could not be substantiated and he tabled a paper putting forward an alternative interpretation of the available data. A copy of this statement can be found on the VMD website.

Steve Dean, the VMD's Chief Executive, provided an update of the measures that had been taken to date to implement the recommendations contained in the Defra Agency Review "Science for Sustainability" that had been published in December 2002. These had included measures to improve the corporate governance of the VMD, an increased Agency role in the development of Defra's Animal Health and Welfare Strategy and the formation of a new Management Board that included two independent external members. As a result of these, and other changes, the VMD's Framework document was being updated and steps were being taken to examine how the VMD's communications with its customers could be improved.

Regulatory Impact Assessments

The VMD was asked to explain how it carried out regulatory impact assessments (RIAs), particularly with regard to consultation with small businesses. VMD explained that the Government was committed to the use of RIAs as a tool to evaluate proposals that impact on businesses, charities or voluntary bodies and could result in legislation. The Medicines Act 1968 required Ministers to consult with "such organisations as appear to them to be representative of interests likely to be substantially affected" before making any Regulation or Order under the Act. VMD explained that from the time it had been established it had endeavoured to consult interested organisations about all proposals for significant changes to legislative controls and operating procedures on veterinary medicines.

The current guidance required a small firms' impact test to be carried out as part of the RIA. The guidance specifically defined a small firm and the impact test consisted of two stages. The first stage required an initial sounding on the

opinions of small firms on the impact of the proposals and would lead to a partial RIA. Where this indicated that the impact was likely to be significant, a further, more detailed exploration of the options was required. Results of the small firm's impact test were included in the partial RIA, which in turn formed part of the formal consultation exercise. VMD went on to explain that where a regulatory impact assessment was considered appropriate, the VMD would initially seek information informally on the likely impact of the proposed changes on business from a sample of relevant organisations. The organisations approached would depend on the issues involved and the VMD may seek nominations from an appropriate umbrella organisation. The required information would normally be obtained by informal enquiries either by telephone, face-to-face meetings or in writing. The information gained would be included in a partial regulatory impact assessment, which would generally form part of the wider consultation exercise.

Herbal Medicinal Products

The VMD was asked whether it had any information on the current situation on the proposed EC Directive on traditional herbal medicinal products and, if a similar category was to be introduced into the veterinary regulations, what safeguards would be put in place to ensure that those companies holding full manufacturing authorisations for veterinary herbal medicines would not be commercially disadvantaged. The VMD explained that the proposed Directive on traditional herbal medicinal products concerned products for human use. It was not aware of any proposals to extend these provisions to veterinary products. The VMD acknowledged that there had been some suggestions to this effect, but it was understood that these had been rejected both by the European Commission and the majority of Member States. The VMD explained that, if, in the future, the European Commission proposed any new provisions in respect of veterinary herbal medicinal products, these would be subject to negotiations in Brussels and the VMD would need to consider the implications of any such proposals, in consultation with the industry and other interested parties, to enable the Government's negotiating position to be determined.

Review 2001

It was noted that discussions in Brussels on the Review 2001 proposals were fast moving, but the VMD were asked for a view on the implementation timetable for the legislation and in particular whether the proposals would be implemented as a whole or piece meal. VMD explained that the timing for completion of the negotiations remained uncertain. There had been agreement on the need to achieve completion before accession of the new Member States in May 2004 and the consequent need to avoid conciliation if possible. It was explained that the proposals contained within Review 2001 were the subject to "co-decision" procedures. This requires agreement by both the European Council and the European

Parliament. Following a first reading of the proposals the Council's common position had been transmitted to the European Parliament for a second reading. The European Parliament will produce second reading reports, which were scheduled to be voted on in a plenary session of the Parliament at the end of November. These would be considered by the Council and, if agreement was not reached, the issue would be referred for conciliation procedures. The European Commission had held meetings with the European Parliament's representatives and the Council Presidency to try to promote agreement between the Council and the European Parliament.

The VMD explained that it was currently proposed to allow Member States 18 months to transpose the Directive's provisions into national legislation once the amending Directive entered into force. The VMD considered that it was most likely that the Directive would be implemented as a whole rather than piece meal because of the need to amend legislation. It was stressed, however, that there would be full consultation on the proposals to implement the Directive.

Article 4 of Directive 2001/82/EC

The VMD was asked to explain what progress had been made on implementing this article in the UK as it was believed that its implementation could increase the range of medicines available for minor pet species. The VMD explained that Article 4 of Directive 2001/82/EC provided an exemption, which Member States may implement, from the need for veterinary medicinal products, intended solely for aquarium fish, caged birds, homing pigeons, terrarium animals and small rodents, to be subject to the full marketing authorisation procedures. The VMD acknowledged that whilst some informal consultations had taken place previously with the Ornamental Aquatic Trade Association and the National Office of Animal Health, little progress had been made due to conflicting priorities and a lack of available time. The VMD gave an assurance that it intended to seek Ministerial approval to consult on detailed proposals before the end of 2003. Subject to Ministerial agreement, formal consultations would start early in 2004.

Standards of competence for non-veterinarians administering veterinary medicines

The VMD was asked for its views on the standards of competence for non-veterinarians administering veterinary medicines and the nationally accredited NPTC certificates of competence in the safe use of animal medicines. The VMD stated that it recognised the role of the NPTC in offering a number of certificates of competence in various aspects of the safe use of veterinary medicines, in particular, the one that was currently recognised in legislation relating to the safe use of sheep dips. The VMD pointed out that there were legislative controls that were designed to ensure that veterinary medicines were only sold or supplied to people with the knowledge of how best to use them or to provide advice on their use. However, the controls on the administration of veterinary medicinal products was covered by the Veterinary Surgeons Act which was outside the remit of the VMD. The VMD suggested that this matter should be discussed with Defra's Animal Health and Welfare Group, the Royal College of Veterinary Surgeons, BVA and the National Farmers

Union as to how best competencies in the safe use, i.e. handling and administration of veterinary medicines, should be addressed. There were issues of how any such competencies could be monitored and it was suggested that the NPTC should be invited to attend a meeting with Responsible Use of Medicines in Animals (RUMA) Alliance, whose work appeared to complement the work of the NPTC.

Animal Health Management Plans

The VMD was asked why the requirements for farms to have an agreed animal health management plan (as introduced in various guidance notes and Codes of Practice) was not being actively encouraged. The VMD explained that Defra had consulted recently on a draft action plan on positive animal health which set out the principles of how it would work with stakeholders in a partnership approach to encourage more widespread, proactive use of farm health planning to improve standards of disease prevention and control. This was seen as a key new initiative under the outline animal health and welfare strategy and Defra would be working closely to foster a culture of good practise in disease prevention and control across all livestock sectors. VMD explained that it was working closely with Defra on how farm health planning could contribute proactively to the linkage between farm health planning and responsible use of medicines.

Medicinal Claims for Veterinary Medicinal Products

The VMD was asked to explain the rules governing medicinal claims for veterinary medicinal products. VMD explained that products which are either presented for the treatment or prevention of disease in animals or which contain active ingredients that have that function, must be authorised under the relevant legislation before they can be legally sold or supplied in the UK. It was accepted by the VMD that there were occasional problems in defining what was meant by a medicinal claim or function. Nevertheless, the VMD sought to operate on a basis of discussions with the companies concerned, to seek to obtain their agreement where it is felt companies are making unsubstantiated medicinal claims. The VMD stated that where necessary it would take a case to the Court. There was some concern at the lack of information on progress provided to those companies or individuals who reported products that were making unsubstantiated medicinal claims. The VMD acknowledged the need to keep complainants aware of progress, but there were problems both of commercial sensitivity and fairness to all parties. Nevertheless, the VMD were looking at how communication could be improved.

The Prescribing Cascade

The VMD was asked what steps it had taken to inform veterinarians that they can prescribe drugs authorised for a different species if the correctly authorised drug is unsuitable e.g. the human phenobarbitone in cases where dogs are sensitive to the higher proportion of lactose or colorant contained in the authorised veterinary product Epiphen. VMD explained that prescribing cascade was established in UK legislation and the interpretation and operation of the provisions had been the subject to much discussion with the veterinary organisations as well as individual veterinary surgeons. In response to these uncertainties, VMD had produced a guidance note – number 8 in the Amelia series.

This gave examples of circumstances in which the cascade options could be followed and included a specific reference to individual characteristics of animals, including known sensitivity to a treatment.

In a question linked to the use of the authorised veterinary medicine Epiphen, to treat epilepsy in dogs, the VMD reported that only five cases of adverse reaction events related to such treatments had been received since the record started. The VMD encouraged veterinarians and owners of animals to report any suspected adverse reactions to veterinary medicines to enable it to take appropriate action, but stressed the need for firm, rather than anecdotal evidence. In a follow-up question, the VMD was asked whether it could do anything about the antioxidants, colorants and preservatives which are being used in certain brands of popular dog food, which it was felt were contributing to the growing cases of epilepsy in dogs. The VMD stated that it had no responsibilities in this area and felt that this was probably one where the Food Standards Agency (FSA) would be involved. It agreed, however, to check the position and write to the organisation concerned once the position had been clarified.

Secretariat Note: It was subsequently confirmed that the FSA were responsible. The organisation concerned has been informed.

Antibiotic Resistance

The VMD was asked whether it was willing to provide the data collection system, which the VPC's Working Group believes to be essential. The VMD explained that the current sales data collection method can break down the data into the format that the VPC has recommended, except in the case of species split, but the VMD was working to achieve this.

The VMD was asked whether a voluntary system could ever provide the accurate data, which is required to carry out this serious scientific work. VMD stated that it believed that the current voluntary sales data collection system does provide accurate data to support serious scientific work. It pointed out that the UK was one of only a handful of countries that collect, collate and publish data of this kind in the world. The UK model is regarded by contemporaries as groundbreaking and is being followed by others.

The VMD was asked whether there was, at present, any independent audit of the published antimicrobial usage data. The VMD explained that sales data was independently audited through a range of methods by an independent consultant during 2002, to validate the VMD database. This had led to a restating of some of the reported figures in the 2001 sales data report. The VMD also checked the information from independently audited company accounts and validated the data calculations in house by trained staff.

The VMD was asked specifically whether it was willing to publish the data for the Fluoroquinolones group in kilograms rather than in tonnes. The VMD confirmed that it was willing to publish the data in kilograms, but pointed out that currently these data were published as tonnes to make them comparable with other data contained in the report.

It was noted that in the most recent antimicrobial usage report, a new method of calculating the quantities of active ingredient had been introduced. This had led to large revisions of previously published figures and the VMD was asked in what way the new method for calculating the quantity of the active ingredient differed from the old method. The VMD explained that the changes made to revise the database included the standardisation of correction factors to convert the sales of product into tonnes of active ingredient to make comparison with the Danish figures more meaningful. In addition, some products were moved between reporting categories because previously they had been incorrectly categorised.

Advertisement and Promotion of Antimicrobials

It was pointed out that the Swann Committee, in its 1969 report, recommended that "the advertisement and promotion of therapeutic antimicrobials to layman should be forbidden". The VMD was asked why the direct advertisement of these drugs to farmers was still permitted and whether it believed that these advertisements were compatible with Swann.

The VMD stated that the advertising of POMs was not aimed primarily at the layman. The advertising was intended to reach all relevant persons involved in animal livestock rearing and food production. The VMD stressed that no POMs can be purchased by a layman, without the treatment being prescribed by a veterinarian. Veterinarians are fully aware of the implications of the use of an antimicrobial and supported the responsible use guidelines issued by RUMA. The VMD went on to explain that there was currently no legal basis to enforce pharmaceutical companies to target their advertising at professionals only, however, proposals contained in the Review 2001 package of legislation may lead to new rules on the advertising of POMs.

Fluoroquinolones

The VMD was asked whether it considered special consideration should be given to how fluoroquinolones were advertised in the press because this drug was a member of a class of active ingredients that may cause cross resistance to agents essential for human therapy. The VMD was asked whether it agreed that adverts should be required to remind vets of the particular dangers associated with excessive fluoroquinolone consumption.

The VMD explained that it was not within its remit to state how a company could market its products within the UK providing that the advertisements were in accordance with the summary of product characteristics. The VMD fully supported the responsible use of all antimicrobials, including fluoroquinolones, and had published a leaflet about this which was available from the VMD website or on enquiry. The VMD pointed out that all fluoroquinolones sold for uses in the UK were prescription only medicines and that, at present, 1.38 tonnes of antimicrobials were sold for use in veterinary medicines in the UK. This was less than 1% of the total antimicrobial sales in the UK annually.

Chairman's Closing Remarks

In the absence of further questions, the Chairman drew the meeting to a close by thanking all those present for attending the meeting and for the useful and open discussions that had taken place.

■ IMPLEMENTATION OF FEE INCREASES FOR INSPECTIONS AND REGISTRATION OF AGRICULTURAL MERCHANTS AND SADDLERS

The Medicines (Exemptions for Merchants in Veterinary Drugs) Order 1998 requires agricultural merchants and saddlers who wish to sell or store certain veterinary drugs to register with the Royal Pharmaceutical Society of Great Britain (RPSGB). An annual fee is payable to the RPSGB for work carried out by the Animal Medicines Inspectorate (AMI) in maintaining this register and carrying out inspections.

This fee is annually revised and is announced in a written Ministerial Statement.

The table below outlines the fees which have been implemented for 2004/5 which were announced in a Ministerial Statement on 26 January 2004.

FEES

Application in respect of each premises	Previous fee	New fee
Agricultural Merchants		
1. For registration under Article 5	£ 232	£ 232
2. For retention of registration under Article 5	153	161
3. For restoration of registration under Article 5	197	197
Saddlers		
1. For registration under Article 5	127	127
2. For retention of registration under Article 5	83	85
3. For restoration of registration under Article 5	107	107

■ ANNUAL LIAISON MEETING WITH REPRESENTATIVES OF CONSUMER ORGANISATIONS

The VMD's annual meeting with representatives of consumer organisations, took place on the afternoon of Tuesday 2 March 2004 in the VMD conference room.

It was preceded by a tour of the VMD building, when representatives had the opportunity to meet staff from the Licensing, SARSS, Policy and Residues Teams. Team members gave short presentations on their subjects and answer questions.

The report of the meeting held in 2003 is available on our website, under 'MAVIS on-line News'. A report of the 2004 meeting will be posted on the VMD website.

■ CONSULTATION ON FEE INCREASES FOR INSPECTIONS AND REGISTRATION OF MANUFACTURERS, DISTRIBUTORS AND INTERMEDIARIES

The Medicated Feedingstuffs Regulations 1998 and The Feedingstuffs (Zootechnical Products) Regulations 1999 require manufacturers, intermediaries and distributors of medicated feedingstuffs and zootechnical feed additives to register with the Royal Pharmaceutical Society of Great Britain (RPSGB). An annual fee is payable to the RPSGB for work carried out by the Animal Medicines Inspectorate (AMI) in maintaining this register and carrying out inspections.

This fee is revised annually and is implemented in the above two sets of Regulations. A consultation letter seeking the views of interested parties on the proposed fee increases for 2004/5 was sent out on 23 December 2003. Recipients can write to the VMD expressing views on the proposed increases by 15 March 2004.

A copy of the consultation package is available on the VMD website: www.vmd.gov.uk.

The table below outlines the proposed fees for 2004/5.

Establishment category	Current annual fee (2003/04)	Proposed annual fee (2004/05)	Amount of increase
	£	£	
Distributor/intermediary	112	124	12
1.3P	100	112	12
AB	115	131	16
1.3M	157	182	25
AA	296	354	58
1.3M (Special)	484	530	46
AA(Special)	484	530	46
1.2 (Premixture)MFS	720	840	120
1.1 (Additive)	720	840	120

Please note that with the exception of distributor/intermediary all the above categories are manufacturers of animal feed. Their fee is linked to the activities for which approval is required. Full details of each activity can be found in the consultation package.

Further information: *Janis McDonald (VMD, 01932 338307, e-mail: j.mcdonald@vmd.defra.gsi.gov.uk) or Phil Davies (VMD, 01932 338420, e-mail: p.davies@vmd.defra.gsi.gov.uk).*

■ HORSE MEDICINES

We have received a number of enquiries on medicines authorised for the treatment of horses due to the new horse passport requirements. We have therefore provided a new area on the web site under 'Publications' and 'Horse medicines' and have published, under a cover page, two separate lists of those veterinary medicines which are authorised to be administered to horses according to whether the animals are intended for human consumption. The lists have been compiled from VMD records as conscientiously as possible, given the amount of data and available resources, and are provided as an additional aid to enquirers.

We expect to update the lists regularly – at least once every month. As we cannot guarantee the complete accuracy or completeness of the lists, interested persons using the list are also advised to consult the current National Office Animal Health (NOAH) Compendium of Data Sheets for Veterinary Products which lists and summarises data on most veterinary medicinal products.

Further information : Heather Oliver (VMD, 01932 338316, e-mail: h.oliver@vmd.defra.gsi.gov.uk).

■ IMPORT OF VETERINARY MEDICINAL PRODUCTS LABELLED FOR THE UK AND OTHER MARKETS AND IMPLICATIONS FOR MARKETING AUTHORISATIONS FOR PARALLEL IMPORT (MAPI)

The VMD has recently become aware that some confusion exists about the rules on the import of veterinary medicines and the requirements for a marketing authorisation for parallel import (MAPI).

Legislation prohibits the marketing or administration (or import for those purposes) of a veterinary medicinal product unless it is the subject of a marketing authorisation valid in the UK – a UK authorised product. The VMD considers that a UK authorised product is one that complies with all the provisions of the UK authorisation, including the UK labelling requirements, and bears the UK authorisation number. This would include products that may additionally be labelled for the market of another country (eg products that are dual-labelled).

A MAPI allows the import and placing on the market in the UK of a product that is authorised in another Member State and is essentially similar to a product authorised in the UK (see AMELIA 9 for further details). It follows that a MAPI is not required for the import and placing on the market of a dual labelled product that is a UK authorised product where this has been legally obtained by a UK authorised wholesale dealer from another Member State in which it is also authorised.

Further information : Heather Oliver (VMD, 01932 338316, e-mail: h.oliver@vmd.defra.gsi.gov.uk).

LICENSING

■ AMELIA 13 GUIDANCE NOTE FOR ANIMAL TEST CERTIFICATES

The Animal Test Certificates (Revocation) Regulation 2003 Statutory Instrument 2003 No.3249, that revoked the current Animal Test Certification (ATC) Regulation 1996 came into force on 12 January 2004. The Regulation revokes the detailed legislative requirements for making an ATC application. These provisions are now set out in the AMELIA 13 guidance note for ATCs, that is published by the VMD. The legal requirement to apply for an ATC in the Medicines Act 1968 has not been changed.

This revision introduces two types of application: Type A and Type B.

Type A

Type A includes applications for trials of products that are already authorised as a human or veterinary medicinal product in an EU member state or by the centralised procedure and either;

- the product is an immunological product and the trial is to be conducted in species included on the existing marketing authorisation;

Or

- the product is a pharmaceutical product and either;

the trial is to be conducted in companion animals only, or

the trial is to be conducted in a food producing species and the existing marketing authorisation (MA) is for the same species and the same or similar dosage regime and method of administration.

The target for processing this type of application is 30 calendar days upon receipt of a valid application with no provision for stopping the clock. For this type of ATC application the fee is £290.00.

Type B

All applications for other trials requiring an ATC, which are not listed above, will fall under the Type B category.

The target for processing this type of application is 50 calendar days upon receipt of a valid application. There is a provision for a Company response to a list of questions and during this time the 'clock' will be stopped. For this type of ATC application the fee is £700.00.

A revised AMELIA 13 giving full details and guidance on procedures is available in hardcopy or from the VMD website www.vmd.gov.uk under both Applications and Publications pages.

Further information on application: Sandra Russell (VMD, 01932 338439 e-mail: s.russell@vmd.defra.gsi.gov.uk)

Further information on policy issues: Jo Cawthorne (VMD, 01932 338317, e-mail: j.cawthorne@vmd.defra.gsi.gov.uk)

■ SPECIFIC BATCH CONTROL – PHARMACEUTICAL PRODUCTS

As set out in the consultation document for the 2003/2004 fees proposal, the VMD has introduced a charge for specific batch control (previously called specific batch exemptions). The new fee became effective on 18 December 2003.

Specific batch control may be requested for pharmaceutical products authorised under an ATC or under a UK Marketing Authorisation that has not been the subject of a Mutual Recognition procedure.

An Information Pack on the Specific Batch Control scheme, which details how the scheme operates and includes a copy of the official request form, can be obtained from **Trudi Newbold (VMD, 01932 338498, e-mail: t.newbold@vmd.defra.gsi.gov.uk)**. The Information Pack is also available on the VMD website.

Further information: Jackie Atkinson (VMD, 01932 338405, e-mail: j.atkinson@vmd.defra.gsi.gov.uk)

■ PUBLIC CONSULTATION ON THE DRAFT VICH GUIDELINE GL 38 ON ENVIRONMENTAL IMPACT ASSESSMENTS (EIAs) FOR VETERINARY MEDICINAL PRODUCTS (VMPs) – PHASE II

VICH (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products) is the process whereby international harmonisation is achieved on the data requirements and protocols used in the regulatory process for veterinary medicines. VICH is a trilateral programme aimed at harmonising technical requirements for veterinary product registration. The parties to VICH are the EU, USA and Japan. In addition, Australia, New Zealand and Canada participate as observers. The nine-step process involves both regulators and the veterinary pharmaceutical industry as equal partners. Once adopted, the VICH recommendations should replace corresponding regional requirements.

The draft VICH guideline GL 38 on Environmental Impact Assessments (EIAs) for Veterinary Medicinal Products (VMPs) – Phase II was signed off at the VICH Ecotoxicity Working Group on 22 - 25 July. The signed off document was considered by the CVMP at its meeting on 14-16 October 2003. The CVMP adopted the draft guideline for release for six months of public consultation. The document CVMP/VICH/790/03-CONSULTATION is available from the EMEA website at <http://www.emea.eu.int/htms/vet/vich/vichdraft.htm>

Comments on the draft guideline can be made through the International Federation of Animal Health for those MA holders who are IFAH members. Comments can also be sent directly to either **Mr Peter Jones, Head of Veterinary Medicines and Inspections Unit** or **Dr Kornelia Grein, Head of Sector, Safety of Veterinary Medicines** at the EMEA by e-mail: peter.jones@emea.eu.int or kornelia.grein@emea.eu.int; or by post (EMEA, 7 Westferry Circus, Canary Wharf, London, E14 4HB).

Further information: Alex Tait (VMD, 01932 338391, e-mail: a.tait@vmd.defra.gsi.gov.uk).

■ EXPORT CERTIFICATES

As set out in the consultation document for the 2003/2004 fees proposal, the VMD has introduced a charge for Export Certificates. The fees are £25.00 per export certificate and £10.00 per copy of the original certificate and became effective on 18 December 2003. Specific batch exemption charges do not apply immunological products.

Further information: Sandra Russell (VMD, 01932 338439, e-mail: s.russell@vmd.defra.gsi.gov.uk).

■ NOTES FOR GUIDANCE

Concept Papers

At the November CVMP meeting the Committee adopted a Concept Paper on the revision of the guideline on plastic primary packaging materials (EMEA/CVMP/1028/03).

At the December CVMP meeting the Committee adopted a Concept Paper on the development of a guideline on the stability test data to be submitted for variation applications to a Marketing Authorisation (EMEA/CVMP/1027/03).

Position Papers

The Committee also adopted the revised Position Paper regarding Availability of Veterinary Medicinal Products – Extrapolation of MRLs (EMEA/CVMP/457/03-Post CONSULTATION) having considered the comments received on its proposals regarding facilitation of MRLs for essential MUMS products during the public consultation.

Adopted Guidelines

The Committee adopted the Revised Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMEA/410/01-Rev.2).

The Committee adopted the Guideline on requirements for concurrent administration of immunological veterinary medicinal products (EMEA/CVMP/550/02-FINAL) following the close of the consultation period.

EMEA/CVMP/422/99-Rev 2 Final
CVMP Note for guidance on declaration of storage conditions
a) in the product information of pharmaceutical veterinary medicinal products;
b) for active substances.

EMEA/CVMP/680/02 Final
CVMP Note for guidance on the quality of modified release dosage forms for veterinary use.

Revised CPMP and CVMP Guideline on Active Substance Master File Procedure
EMEA/CVMP/134/02 CPMP/QWP/227/02
Implementation date: 31 August 2004.

Guides out for Consultation

The Committee for Veterinary Medicinal Products (CVMP) at its October 2003 meeting adopted the draft VICH guideline GL 38 on Environmental Impact Assessments (EIAs) for Veterinary Medicinal Products (VMPs) – Phase II for release for six months of public consultation (EMEA/CVMP/790/03-CONSULTATION).

The Committee also adopted the Position Paper on Data Requirements for Removing the Target Animal Batch Safety Test for Immunological Veterinary Medicinal Products in the EU (EMEA/CVMP/865/03-CONSULTATION) for release for three months of public consultation.

EMEA/CVMP/540/03 Consultation
CVMP Note for guidance on quality aspects of pharmaceutical veterinary medicines for administration via drinking water.

EMEA/CVMP/541/03 Consultation
CVMP Note for guidance on the chemistry of new active substances.

Copies of these documents are available from the EMEA or can be found on the EMEA website at <http://www.emea.eu.int>.

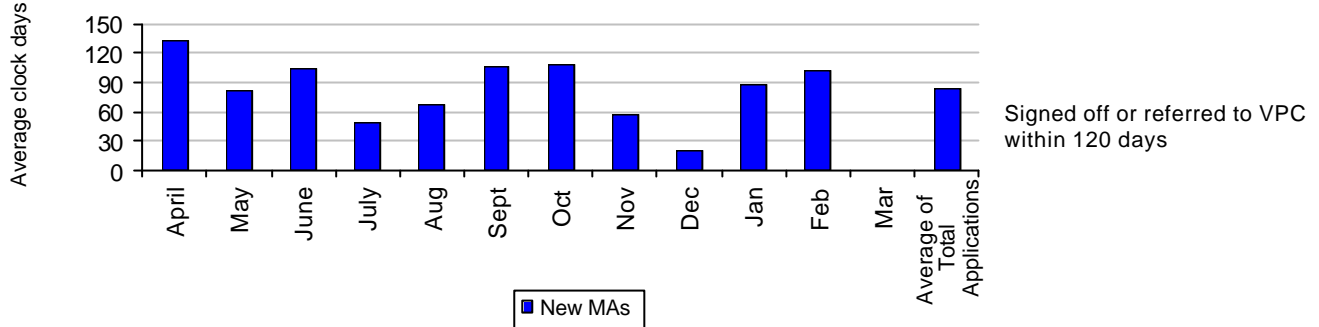
LICENSING BUSINESS PERFORMANCE AGAINST TARGETS

The Licensing Business is committed to providing information on our performance and to allow stakeholders to monitor our performance against targets throughout the year, rather than once a year in the VMD Annual Report. The attached charts represent this aim and depict, on a monthly basis, the average number of days taken to complete the target defined in the legend to each figure. The last column on the right of each figure represents the overall average achieved during the financial year and the text to the right represents the average day target. We would be grateful for feedback from readers as to how easy they find these charts to understand and if they contain useful information. Suggestions on how they might be improved will be welcome and we will amend the charts in light of comments received.

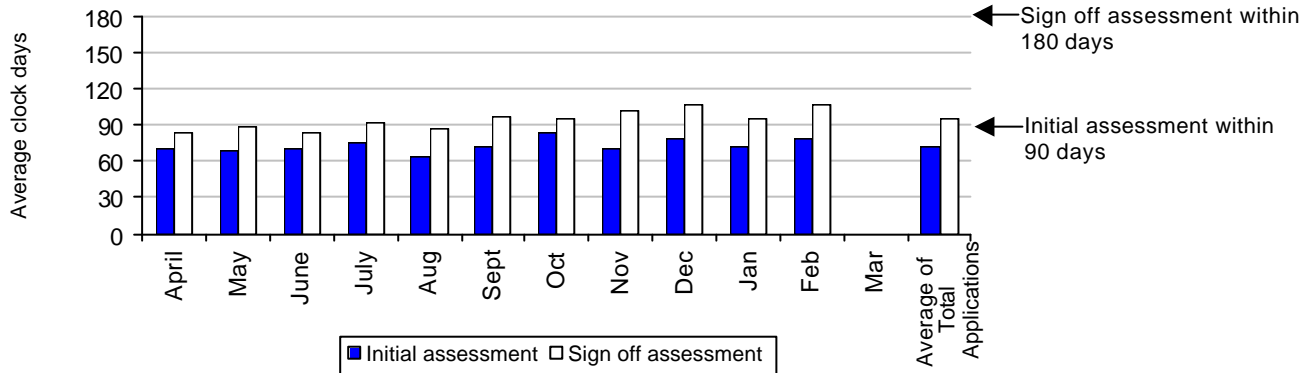
Further information on figures and charts: **Lea Stott** (VMD, 01932 338432, e-mail: l.stott@vmd.defra.gsi.gov.uk). For information in relation to licensing business performance contact **John O'Brien** (VMD, 01932 338387, e-mail: j.o'brien@vmd.defra.gsi.gov.uk).

New Marketing Authorisations

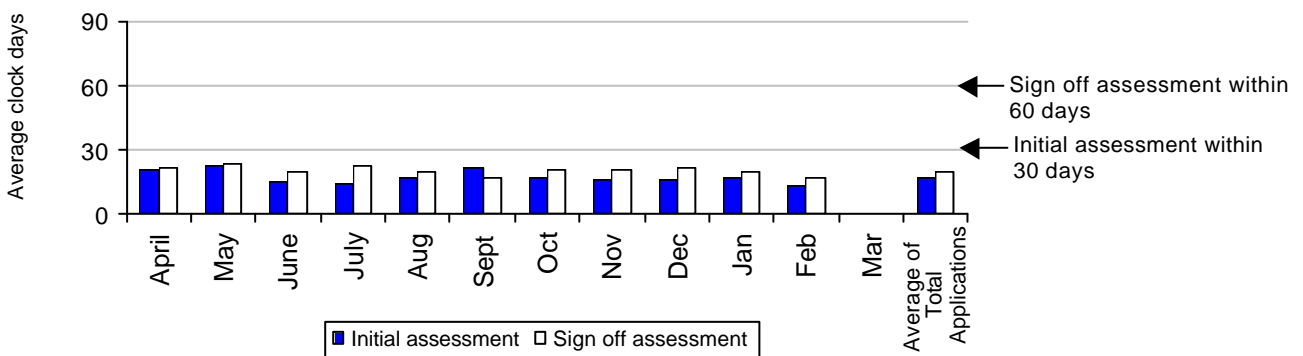
TARGETS (average clock days)



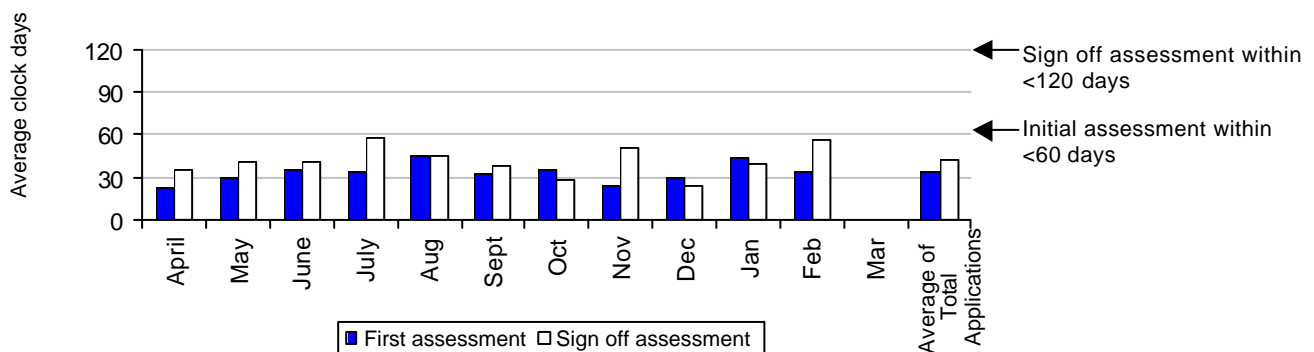
Renewals



National Type I Variations



National Type II Variations



■ ELECTRONIC RESPONSE PROCEDURES

We would like to remind you of our e-mail response procedures and clarify our submission procedures.

We are open as usual for all data deliveries from Monday to Thursday 8.30am to 5.00pm, and until 4.30pm on Fridays.

We are happy to accept electronic letters and responses on letter headed paper to a maximum of 2 pages to this e-mail address s.response@vmd.defra.gsi.gov.uk. We will only accept electronic responses sent to this official address. Any electronic submissions sent directly to Assessors or any other e-mail address will not be acknowledged or treated as a 'clock starting' response. Any larger submissions must be sent via Courier.

Although not our preference, we also accept responses up to 10 pages via fax, but please ring us in advance to alert us to this means of communication.

Please submit electronic responses to Information Management on s.response@vmd.defra.gsi.gov.uk. We are also happy to receive data via the Eudralink service at this e-mail address (direct line 01932 338448).

Further information: Suzanne Pearce (VMD, 01932 338444, e-mail: s.pearce@vmd.defra.gsi.gov.uk).

■ NUMBERS OF ATCs RECEIVED AND DETERMINED BETWEEN 31 SEPTEMBER 2003 AND 31 DECEMBER 2003

No. ATCs Received	9
No. ATCs Issued	8
Stopped at End Quarter	
No. Refused at Validation	1
No. Withdrawn during Assessment	0

Time taken for Assessment of Issued ATCs

Range of Days	0-15	16-31	32+
No. of Applications	3	4	1

Average Days = 16

Time during which these issued applications were with the company dealing with outstanding questions

Range of Days	0-30	31-63
No. of Applications	6	2

Average Days = 14

Total time from validation to determination

Range of Days	0-30	31+
No. of Applications	6	2

Average Days = 28



■ EUROPEAN REVIEW OF VETERINARY MEDICINES LEGISLATION

A new section that is dedicated to the European Review of Veterinary Medicines Legislation (Review 2001) is now on the VMD website, www.vmd.gov.uk, and can be located under 'Publications' and then 'Review 2001'.

The website contains the documents that were presented at the meeting held for the Review consultation group at the VMD on 6 January 2004. Also included on the website is an 'Unofficial Draft Consolidated Directive on Veterinary Medicinal Products'.

Further information: Geoff Long (VMD, 01932 338319, e-mail: g.long@vmd.defra.gsi.gov.uk) or Heather Oliver (VMD, 01932 338316, e-mail: h.oliver@vmd.defra.gsi.gov.uk).

ENFORCEMENT

A key element in our strategy for assuring the safety, quality and efficacy of veterinary medicines is the action that we take against the illegal marketing and use of unauthorised products and to promote the responsible use of authorised products. This section describes the most significant developments and outcomes in this area.

■ ENFORCEMENT ACTIVITY

The VMD enforcement team was established five years ago to combat the illegal importation and sale of veterinary medicines and the illegal marketing and sale of unauthorised veterinary products. Its five dedicated staff work closely with other Government bodies, including our equivalent body in the Republic of Ireland, Defra's Investigation Officers and legal team, as well as inspectors from Animal Medicines Inspectorate (AMI) of the Royal Pharmaceutical Society of Great Britain (RPSGB).

Current cases

Currently the team is actively pursuing 138 cases concerning the marketing of unauthorised veterinary products. A further 61 cases are currently under investigation or with prosecution lawyers pending possible legal proceedings. Last year Defra lawyers took nine cases on our behalf, all of which ended in successful prosecutions with fines ranging from £450 to £13,500.

Use of arable cypermethrin

In addition the enforcement team has been actively involved in an on-going investigation in West Wales into the illegal use of arable cypermethrin to dip sheep. Although responsibility for enforcement in Wales rests with the Welsh Assembly, our enforcement team is working closely with them and representatives have attended two meetings of stakeholders held at the Welsh Assembly's offices in Cardiff to discuss the measures that need to be taken to stop this illegal use.

ATTENDANCE AT TRADE SHOWS

Over the last year the enforcement team has attended 30 exhibitions/trade fairs and shows country wide, both to actively promote its work and to investigate any illegal marketing or supplying veterinary products. Details of the shows visited can be found on the VMD's website (www.vmd.gov.uk). We intend to visit a similar number of shows this year.

VETERINARY MEDICINES-DO YOU NEED A MARKETING AUTHORISATION?

We recently revised our guidance booklet 'Veterinary Medicines - Do You Need a Marketing Authorisation?'. This booklet gives guidance on what makes a product fall within the definition of a veterinary medicinal product, and under what circumstances a product can be marketed without a marketing authorisation. Copies are available free of charge from Barry Haycraft (VMD, 01932 338308, e-mail: b.haycraft@vmd.defra.gsi.gov.uk).

■ CONSULTATION ARTICLE - 4

The VMD are currently consulting interested parties on proposals to implement the exemption under Article 4 of Directive 2001/82/EC of the European Parliament on the Community Code relating to Veterinary Medicinal Products. This permits member states to exempt a range of veterinary medicinal products from the requirements for a marketing authorisation, subject to certain conditions being met. It is proposed to implement this exemption in the UK in a way that will minimise the risk to the animals and their owners. It will apply to veterinary medicinal products placed on the UK market which are labelled exclusively for use in one or more of the following categories: aquarium fish, cage birds, homing pigeons, terrarium animals and small rodents.

Further information together with the full consultation package can be found on the VMD website: www.vmd.gov.uk.

Further information: Simon Hack (VMD, 01932 338306, e-mail: s.hack@vmd.defra.gsi.gov.uk) or Barry Haycraft (VMD, 01932 338308, e-mail: b.haycraft@vmd.defra.gsi.gov.uk).

ANTIMICROBIAL RESISTANCE

Antimicrobial resistance is a serious problem in human and veterinary medicines, resulting in increasing concerns about the use of antimicrobial products in human medicines, veterinary medicine, animal production, agriculture and horticulture. A Government Strategy has been developed to address this issue. The Veterinary Medicines Directorate is responsible for delivering key elements of this strategy, including the collection and publication of information on the quantities of antimicrobial products sold each year for veterinary use in the UK and providing a secretariat to the Defra Antimicrobial Resistance Coordination (DARC) Group. The following articles describe the most recent actions that the VMD has taken to progress this strategy.

■ DEFRA ANTIMICROBIAL RESISTANCE COORDINATION (DARC) GROUP MEETING

The Defra Antimicrobial Resistance Coordination (DARC) Group met on 25 November 2003. Items discussed included progress on developing a strategy for surveillance of veterinary antimicrobial resistance, tracking progress with implementing the recommendations made in the ACMSF Report, the 2002 Antimicrobial Sales Data Report, the production of a comparative list of human and veterinary antibiotics and the work of the Specialist Advisory Committee on Antimicrobial Resistance (SACAR) Veterinary Sub-Group. The Responsible Use of Medicines in Animals (RUMA) Alliance also gave the Group a presentation on its work.

Further details of the DARC Group can be obtained from **Dr Kay Goodyear (VMD, 01932 338409)**. Details of the RUMA Alliance can be found on their website at www.ruma.org.uk/.

■ SALES DATA REPORT

VMD published its Annual Report on Sales of Antimicrobials, Antiprotozoals, Antifungals, Growth Promoters and Coccidiostats in the UK in November 2003. This was several months earlier than in previous years. This year's report has been developed to include information on the sales of antifungals, sub-divide some of the larger reporting categories to provide additional detail on their use, and to apportion the sales of products into three categories: those indicated for use in food-producing animals only, those indicated for use in non-food-producing animals only and those indicated for use in both.

Total sales of therapeutic antimicrobials in the UK remained relatively steady in 2002, compared to previous years, with sales of 457 tonnes of active ingredients (a.i.) for use in all animals. Approximately 88% of these sales were for use in food-producing animals only, but it is not possible to identify what proportion of these were administered to animals that did not enter the food chain. Less than 1% of total sales of therapeutic antimicrobials were fluoroquinolone products.

Sales of therapeutic antiprotozoals in 2002 were 27 tonnes a.i., continuing a downward trend in sales of these products, while sales of veterinary antifungals rose in 2002 to 2 tonnes a.i. There was a decrease in sales of antimicrobial growth promoters to 27 tonnes a.i. in 2002 compared to 2001. Sales of coccidiostats increased to 250 tonnes a.i. in 2002, the highest of the five reporting years.

Copies can be obtained from the VMD website at www.vmd.gov.uk under the publications and general tabs, or from **Dr Kay Goodyear (VMD, 01932 338409)**.

■ OTHER ANTIMICROBIAL ISSUES

VMD, along with other DARC Group Members, was represented at an International Symposium in Berlin, in November 2003 entitled 'Towards a Risk Analysis of Antibiotic Resistance'. Further information from the Symposium can be found at the following web site: www.bfr.bund.de/cms/detail.php?template=internet_en_index_is

The VMD was also invited by a Working Party set up by the US Congress to contribute to their exploration of methods for collating veterinary antimicrobial consumption data. The Working Party had already interviewed Danish colleagues to find out how their electronic prescription information capturing system worked. The VMD provided details of the UK's data collection system. The Working Party will now be considering the information obtained from both the UK and Denmark with a view to developing a veterinary antimicrobial consumption data collection system for the USA.

VMD, in collaboration with colleagues at the Department of Health and The Health Protection Agency, is developing a list of comparable human and veterinary antimicrobials for publication. Both DARC and SACAR believe that this will be a valuable tool for medical and veterinary practitioners and trainees.

SUSPECTED ADVERSE REACTION SURVEILLANCE SCHEME

The definition of a Suspected Adverse Reaction (SAR) is taken from article 1, paragraph 10, of the Directive 2001/82/EC: "adverse reaction means a reaction which is harmful and unintended and which occurs at doses normally used in animals for the prophylaxis, diagnosis or the modifications of physiological function". The definition of a human adverse reaction is taken from article 1, paragraph 11, of Directive 2001/82/EC "... means a reaction which is noxious and unintended and which occurs in a human being following exposure to a veterinary medicine." In addition to this, the UK also include reports of suspected lack of expected efficacy, reports of off-label use of veterinary medicines, reports of environmental incidents and reported violations of approved maximum residue limits arising from the use of a veterinary medicinal product.

■ QUARTERLY REPORT

During the period 1 October to 31 December 2003, the VMD received 429 suspected adverse reaction reports involving animals. Of these, 43 reports related to unauthorised use, 12 involved non-authorised or unidentified products and 32 reports were considered likely to be not product related. There were nil reports involving animal trials under Animal Test Certificates (ATCs) and 45 reports involved suspected lack of efficacy.

The remaining 297 suspected adverse reaction reports were associated with 128 licensed products.

The 297 reports were divided by marketing categories as follows:

- 273 Prescription Only Medicine (POM)
- 17 Pharmacists and Merchants List (PML)
- 1 Pharmacists List (P)
- 6 General Sales List (GSL).

During the quarter, 24 reports of human suspected adverse reactions were received. All human incidents are considered by the Appraisal Panel for Human Suspected Adverse Reactions to Veterinary Medicines. The information thus accrued is analysed to identify any trends or signals that need attention.

During the quarter, SEPA forwarded three reports of environmental incidents attributed to veterinary medicines. All were historical reports. The incidents occurred in July 2002, March 2003 and September 2003. Two incidents were due to badly maintained dipping facilities and/or poor dipping practice. The third incident resulted from a spillage of sheep dip chemical onto a road bridge.

This Quarterly Report will be presented to The Veterinary Products Committee at their meeting in January 2004.

The Quarterly Report for the period 1 July 2003 to 30 September 2003 was presented to the VPC in November 2003.

Further information: Denise Burge (VMD, 01932 338427, e-mail: d.burge@vmd.defra.gsi.gov.uk).

■ EUDRALINK - SECURE ELECTRONIC TRANSFER OF DOCUMENTS

The SARSS team and a small group of Marketing Authorisation Holders (MAHs) have been running a trial to test a secure method (Eudralink) of sending Suspected Adverse Reaction reports to and from the VMD by electronic mail. The Eudralink trial proved to be effective and useful to all participants and we have received very positive feedback. We would now like to extend the use of the Eudralink system to all MAHs reporting to the VMD/UK.

Further information and application forms: Denise Burge (VMD, 01932 338427, e-mail: d.burge@vmd.defra.gsi.gov.uk).

■ CHANGE IN PREFIX FOR ADVERSE REACTION NUMBERS

The SARSS team has recently changed the prefix for adverse reaction numbers to ADR. The prefix ARN will no longer be used. MAHs are asked to note this change and ensure that their PSURs reflect it. All suspected serious adverse reactions and human adverse reactions reported within 15 calendar days should be included in PSURs. Adverse reaction numbers allocated by the SARSS team and notified to MAHs should be included in the details of the relevant cases reported in PSURs.

Further information: Fabia Dyer (VMD, 01932 338424, e-mail: f.dyer@vmd.defra.gsi.gov.uk).

VETERINARY PRODUCTS COMMITTEE

The Veterinary Products Committee (VPC) was set up in 1970 under Section 4 of the Medicines Act. Its terms of reference are:

- *to give advice with respect to safety, quality and efficacy in relation to the veterinary use of any substance or article (not being an instrument, or appliance) to which any provision of the Medicines Act is applicable; and*
- *to promote the collection of information relating to suspected adverse reactions for the purpose of enabling such advice to be given.*

Officials from the VMD, Department of Health, Health and Safety Executive, Environment Agency and Food Standards Agency attend all meetings as advisers to the Committee.

The VPC held meetings on 16 October, 20 November and 18 December. It reviewed and confirmed the minutes of its previous meetings and considered the following matters relating to the authorisation of veterinary medicines. All conclusions reached are subject to review and confirmation at its next meeting.

■ OCTOBER MEETING

Applications

The Committee examined evidence relating to the meat withdrawal period of a product currently authorised for use in cattle and sheep.

The Committee provisionally concluded (subject to confirmation at its next meeting) that the withdrawal period should remain at 56 days and that officials should raise with the EC Committee for Veterinary Medicinal Products the question of how the meat withdrawal period has been set in member states.

General

The Committee considered the contents of a report on proposed changes to the Procedures for Reporting Suspected Adverse Reactions to Veterinary Medicinal Products to the VPC.

The Committee considered and commented upon the potential role of the Environmental Panel in supporting the work of the VPC.

The Committee also considered and commented upon a report on Sales of Antimicrobial Products Used as Veterinary Medicines, Growth Promoters & Coccidiostats In the UK in 2002.

The Committee took note of the quarterly return of Central Register of Members' Interests. Copies of the returns are available on the VPC website www.vpc.gov.uk or from the VPC Secretariat at the VMD, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS (Tel: 01932 338491, Fax: 01932 336618, or e-mail: vpc@vmd.defra.gsi.gov.uk).

Corrected VPC Summary Minutes for the meeting of 18 September 2003 are available on the VPC website or by request from the VPC Secretariat.

It also received the following papers for information, which are publicly available:

- Copies of *The Veterinary Record* contents (front page) "This Week's Issue" for the period 13 September to 4 October 2003 (further information www.vetrecord.co.uk).
- Updated List of Attendees for Open Forum.
- IGHR Report - Uncertainty Factors: Their use in Human Health Risk Assessment by UK.

Additionally it received the following papers, which are not available for publication:

- Report from the Scientific Secretariat and the Biological Committee.
- Report to the VPC on current ATC applications.
- Post-marketing surveillance programme on Rabies Vaccines.
- CVMP Assessment Report EMEA/CVMP/545/03-FINAL.
- VMD Correspondence relating to an application for a feed additive under the terms of European Community legislation, for which the United Kingdom is a Concerned Member State.

■ NOVEMBER MEETING

Marketing Authorisations

The Committee was informed that Ministers had considered its advice on the meat withdrawal period for a product currently authorised for use in cattle and sheep and had concluded that, on legal grounds, the meat withdrawal period should be extended to 70 days.

The Committee examined evidence relating to an application for a marketing authorisation for an anticoccidial product for use in chickens.

The Committee provisionally concluded (subject to confirmation at its next meeting) that the application should be recommended for authorisation subject to certain conditions being met by the applicant.

General

The Committee considered and commented upon the Draft Report of the VPC Open Forum held on 15 October 2003. It agreed that the corrected Report could be made available on the VPC website www.vpc.gov.uk or by request from the VPC Secretariat.

The Committee considered and commented upon the Draft Action Plan to take forward the recommendations in the COT Report - Risk Assessment of Mixtures of Pesticides and Similar Substances.

The Committee also considered the contents of the third SARSS Quarterly Report for 2003 for the period 1 July to 30 September 2003.

Corrected VPC Summary Minutes for the meeting of 16 October are available on the VPC website or by request from the VPC Secretariat.

It also received the following papers for information, which are publicly available [see direct link: Public Papers] or by request from the VPC Secretariat.

- Copies of *The Veterinary Record* contents (front page) "This Week's Issue" Vol. 153, nos. 16-20, (further information www.vetrecord.co.uk).
- Copy of the presentation on Aquatic Medicine at the VPC Open Forum.

Additionally it received the following papers, which are not available for publication:

- Report to the VPC on current ATC applications.
- Report of the Ecopharmacovigilance Working Group 2003.
- CVMP Assessment Report Periodic Safety Update Report for a recombinant vaccine for the active immunisation of cats against feline leukaemia.

■ DECEMBER MEETING

General

The Committee considered and commented upon a further revision of the CODEX Committee Working Group's Draft Code of Practice to Minimize and Contain Antimicrobial Resistance.

The Committee also considered and commented upon proposals for updating the summary minutes of its meetings.

Corrected VPC Summary Minutes for the meeting of 20 November 2003 are available on the VPC website www.vpc.gov.uk or by request from the VPC Secretariat.

It also received the following papers for information, which are publicly available by request from the VPC Secretariat:

- Copies of *The Veterinary Record* contents (front page) "This Week's Issue" Volume 153 Nos 21 - 24 (further information: www.vetrecord.co.uk).
- FSA Annual Report on Research.
- List of Members with effect from 1 January 2004.
- Public consultation on the draft VICH Guideline GL 38 on Environmental Impact Assessments (eias) for veterinary medicinal products (vmpps) – Phase II.

Additionally it received the following papers, which are not available for publication:

- Report from the Scientific Secretariat and the Biological Committee.
- Report to the VPC on current ATC applications.
- Quarterly report of Special Treatment Authorisations issued.

RESIDUES CONTROLS & MONITORING

The VMD operates two complementary surveillance programmes for residues of veterinary medicines and other substances. The larger programme, the National Surveillance Scheme (NSS), implements EU legislation and therefore has a statutory basis. This programme covers the products set out below, and is funded by the industry sectors in accordance with EU legislation.

The second programme is smaller and non-statutory. It focuses more on surveillance of imports of certain products where the presence of banned substances are most likely to be found. The programme is funded by Defra.

The independent Veterinary Residues Committee scrutinises and advises on the content of the VMD's (and FSA's) surveillance work.

■ STATUTORY SURVEILLANCE IN 2003

The National Surveillance Scheme (NSS) operates in accordance with the requirements of Annexes I-IV of Directive 96/23/EC and Decision 97/747/EC. All countries in the European Union must carry out targeted surveillance for residues of veterinary medicines in a range of animals and animal products, including red meat, poultry, farmed fish (salmon and trout), milk, eggs, honey and wild and farmed game.

The results of analyses completed between 1 January 2003 and 5 January 2004 are given in the accompanying tables. Details of the positive samples are given below. Totals reported are the cumulative results for the period.

Authorised officers collect samples from farms, slaughterhouses and egg packing stations. Where confirmed residues of authorised substances are found above the Maximum Residue Limit (MRL) *, a veterinary officer of the State Veterinary Service carries out an investigation at the farm of origin to establish the source of the residue.

Where unauthorised substances or high concentrations of authorised substances are detected, an Investigation Officer from the Department for Environment, Food and Rural Affairs (Defra) Legal Division will undertake an investigation.

■ RED MEAT

Up to 5 January 2004 18,950 analyses had been completed on 19,912 samples. 22 samples were found to contain residues of veterinary medicines in excess of the Maximum Residue Limit/Action Level **.

Synthetic Steroids, Beta-Agonists and Natural Hormones

Three samples of cattle serum out of 338 tested have confirmed positive for progesterone at concentrations of 1 µg/l, 1.1µg/l and 1.6µg/l. The SVS has completed follow-up investigations into the residues of 1.1µg/l and 1.6µg/l and there was no evidence of abuse of this substance on the farms in question. It is probable that the

concentrations detected were due to natural causes. Officers of the SVS will carry out a follow-up investigation into the residue of 1 µg/l.

Two samples of cattle serum out of 355 tested have confirmed positive for testosterone at concentrations of 1 µg/l and in excess of 1 µg/l. These samples have been followed up by the SVS. In one case the residue was likely to have been natural as the sampled animal was pregnant when the sampling took place and further sampling will take place after she has calved. In the second case no evidence of abuse of testosterone was found and five follow-up samples taken from other animals on the farm tested negative.

One sample of sheep urine out of 146 tested has confirmed positive for a residue of nortestosterone at 18µg/l. The follow-up visit indicated no evidence of abuse of this substance and the investigating officer considered it was probable that this residue was a natural occurrence as the animal was an entire male.

Zeranol

One sample of cattle urine out of 244 tested has confirmed positive for a residue of zeranol. The analysis carried out on this sample indicates that this is the result of ingestion of feed contaminated by the fusarium fungus, rather than any abuse of this substance.

Antimicrobials

5,601 samples of kidney from calves, cattle, sheep, pigs and goats have been screened for a range of antimicrobial substances. One sample of pig's kidney out of 819 analysed proved positive for a residue of chlortetracycline at a level of 860µg/kg. The follow-up visit indicated that this residue was probably the result of inadequate feed bin management.

Nitrofurans

A residue of the nitrofurans metabolite semicarbazide has been confirmed in one sample of sheep kidney out of 93 tested. The concentration detected was well below the MPRL (Minimum Required Performance Limit)*** of 1µg/kg set by the Commission. A second laboratory also confirmed the presence of this residue. The use of nitrofurans in food producing animals in the EU is prohibited. The follow-up investigation revealed no evidence of the use of nitrofurans on the farm in question.

Anthelmintics

2,120 samples of liver from goats, cattle, pigs, sheep and horses had been screened for a range of anthelmintics. Three samples of sheep liver out of 404 screened for benzimidazoles have confirmed positive for residues of fenbendazole and oxfenbendazole at levels of 660µg/kg, 840µg/kg and 4,390µg/kg (MRL 500µg/kg) respectively. The SVS has completed its investigation into the cause of the residue of 660µg/kg. They found that lambs on the farm had been treated with products containing benzimidazoles. The animal in question had been slaughtered before the withdrawal period had elapsed. The carcase was returned to the farmer for his own consumption. The SVS will carry out a follow-up visit to investigate the residue of 840µg/kg. The residue of 4,390µg/kg has been referred to Defra for investigation in view of the level detected.

NSAIDs

One sample of horse plasma out of 28 tested has confirmed positive for a residue of phenylbutazone. As no MRL has been set for this substance the case has been referred for investigation.

Ionophores

One sample of pig's liver, out of nine tested, has confirmed positive for a residue of the ionophore Salinomycin at a level of 11µg/kg. Salinomycin is a zootechnical feed additive and should only be used under the terms of its entry in the Annexes to Directive 70/524EC (as amended). The SVS is carrying out a follow-up investigation into the cause of this residue.

Heavy Metals

Ten samples of horse kidney out of 11 tested, contained residues of cadmium at concentrations between 5,700µg/kg and 68,200µg/kg. There is an agreement with slaughterhouses that horse offal will be discarded and therefore it will not enter the food chain.

■ POULTRY

By 5 January 2004 the laboratory had completed a total of 7,636 analyses on 7,645 samples.

Antimicrobials

Three samples of poultry kidney were confirmed positive for residues of chlortetracycline (CTC) above the MRL of 600µg/kg. One sample of hen kidney out of 11 analysed contained a residue of CTC at a concentration of 1,300µg/kg. The investigation into the cause of this residue concluded that cross-contamination of feed on the farm was the most likely cause. One sample of broiler kidney out of 264 analysed contained a residue of CTC at a concentration of 780µg/kg and one sample of turkey kidney out of 79 analysed contained a residue of CTC at a concentration of 860µg/kg. The follow-up visit into the broiler residue indicated that the likely cause was cross-contamination of feed. The SVS will carry out a follow-up investigation into the cause of the residue detected in the turkey sample. Toxicological advice is that these residues do not pose a risk to human health.

Monensin

Two samples of broiler liver out of 261 tested have confirmed positive for residues of the ionophore monensin at levels of 25µg/kg and 2.5µg/kg. The investigation into the residue of 25µg/kg suggested that cross-contamination due to inadequate feed bin management was the likely cause of this residue. In the other case an error at the mill, meaning the wrong feed was delivered, was suspected.

Nicarbazin

250 samples of broiler liver had been analysed by 5 January 2004. 46 have confirmed positive at concentrations between 205µg/kg and 5,520µg/kg. The SVS are investigating these residues at the farm of origin. Investigations into 37 of these results had been completed. The Investigating Officers were not able to identify the cause of the residue in all cases. Possible cross-contamination of feed via the use of a single bin system was considered to be the most likely cause of the residues in the majority of these samples. Contamination at the mill or during transport was also considered as a likely cause for some of these residues. In other cases the use of surplus feed transferred from another farm may have resulted in contaminated feed being fed to the birds during withdrawal. The Veterinary Residues Committee's Feed subgroup met in August 2003 to consider the results and identify ways of reducing the incidence of these residues.

One sample of hen's feed and one of broiler feed taken as a result of the follow-up investigations into these positives have confirmed positive for levels of nicarbazin. The Animal Medicines Inspectorate of the Royal Pharmaceutical Society can be asked to investigate the feed mill if there is an indication that feed contamination is a possible cause of the residue.

■ FARMED FISH

By 5 January 2004, 1,398 analyses had been completed by the laboratory on 1,676 samples. 18 samples – 12 trout and six salmon – contained residues above the Action Level. 11 of the trout and one of the salmon samples are follow-up samples taken as a result of earlier positive sampling.

Malachite/leucomalachite green

Twelve samples of trout out of 87 analysed contained residues of leucomalachite green at concentrations between 2.4µg/kg-62.4µg/kg. One of the samples also contained a residue of malachite green at a concentration of 2.86µg/kg. Six of these samples are follow-up samples following the confirmation of residues of malachite and leucomalachite green in a 2002 trout sample. Movement restrictions have been placed on fish at the farm in question and the case is being considered by Defra lawyers. Of the other six samples five are follow-up samples to a 2003 sample from another site which confirmed positive for malachite green. Movement restrictions have also been placed on this site and the case is being considered by Defra lawyers.

Two samples of salmon have confirmed positive for residues of malachite green and leucomalachite green at

concentrations of 8.4µg/kg (malachite green) and 376µg/kg (leucomalachite green) and 4.8 (malachite green) and 18.9 (leucomalachite green). Four further samples contained residues of leucomalachite green at concentrations between 2.3µg/kg and 5µg/kg. One of these positives is the result of further sampling undertaken as part of the investigation into the original positive samples by officers from the Fisheries Research Services.

■ MILK

Sample collection commenced in February 2003 and 2,257 analyses have been completed on 835 samples. One sample confirmed positive for the presence of the Mycotoxin Aflatoxin M1. The on-farm investigation indicated that this was probably the result of feed contamination and a further milk sample was taken.

■ EGGS

Sample collection commenced in April 2003 and 1,133 analyses have been completed on 535 samples. By 5 January 2004, 26 samples had confirmed positive for the presence of lasalocid. Officers of the State Veterinary Service are investigating the cause of these residues and have completed 18 follow-up visits. In most of the cases cross-contamination of the feed, either at the feed mill or during delivery, was suspected. In two cases there was no evidence of the use of lasalocid on the farms concerned.

11 samples of feed taken as part of the investigations into these residues have confirmed positive for lasalocid at levels between 140µg/kg and 1,380µg/kg. (Two of these

are samples taken in 2003 as a result of 2002 confirmed positives). The Animal Medicines Inspectorate of the Royal Pharmaceutical Society can be asked to investigate the feed mill where there is an indication that feed contamination is a possible cause of the residue.

■ GAME

Sample collection commenced in July. Up to 5 January 2004, 231 analyses had been completed. One sample of partridge muscle confirmed positive for a residue of lead at a level of 33,953µg/kg.

Further information: Janet Rubidge (VMD, 01932 338328, e-mail: j.rubidge@vmd.defra.gsi.gov.uk).

* The Maximum Residue Limit (MRL) is the maximum concentration of residue resulting from the use of a veterinary medicine that is legally permitted or recognised as acceptable in or on a food.

** The Action Level is the concentration equal to the Maximum Residue Limit (MRL) where this has been set, or the Limit of Quantification where no MRL has been set. Where a substance has been entered into Annex IV of Council REGulation (EEC) 2377/90 (i.e. human consumption at any level is unsafe), any confirmed residue will be reported as in excess of the Action Level.

*** The Minimum Required Performance Limit (MRPL) sets an analytical standard which all Member States are required to meet. Commission Decision 2003/181 set levels of 0.3µg/kg and 1µg/kg for chloramphenicol and nitrofurans metabolites respectively.

NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN RED MEAT RESULTS OF TARGETED SAMPLING IN GREAT BRITAIN: 1 JANUARY 2003 – 5 JANUARY 2004

Type of Compound\Substance	Species	Age & Sex	Matrix	No. of Analyses	No. above Action Level
■ 1 Hormones					
Stilbenes	Cattle	< 24	Urine	252	
	Pigs		Urine	141	
	Sheep		Urine	69	
Methyltestosterone	Pigs		Feed	23	
	Pigs		Urine	103	
	Sheep		Urine	68	
Nortestosterone	Cattle		Serum	158	
	Cattle		Urine	145	
	Sheep		Urine	146	1
Oestradiol	Cattle	Male	Serum	309	
Progesterone	Cattle	Male	Serum	338	3
Testosterone	Cattle	Female	Serum	355	2
Trenbolone	Cattle		Serum	169	
	Cattle		Urine	156	
	Pigs		Urine	113	
	Sheep		Urine	160	
	Cattle	< 24	Urine	244	1
Zeranol	Pigs		Urine	104	
	Sheep		Urine	62	
■ 2 Pesticides Including PCBs					
Carbamates	Calves	< 6	Liver	51	
	Pigs		Liver	51	
	Sheep		Liver	241	
Pyrethroids	Calves	< 6	Liver	63	
	Pigs		Liver	63	
	Sheep		Fleece	77	
	Sheep		Liver	386	
	Sheep		Liver	386	

Type of Compound\Substance	Species	Age & Sex	Matrix	No. of Analyses	No. above Action Level	
OC/PCBs	Cattle		Kidney fat	55		
	Pigs		Kidney fat	54		
	Sheep		Kidney fat	106		
Organophosphorus	Sheep		Kidney fat	37		
	Cattle		Kidney fat	196		
	Pigs		Kidney fat	155		
	Sheep		Kidney fat	422		
	3 Beta-Agonists	Calves	< 6	Liver	33	
		Cattle	< 24	Feed	452	
	Cattle	< 24	Liver	461		
	Horses		Liver	10		
	Pigs		Feed	35		
	Pigs		Liver	519		
	Sheep		Liver	400		
4 Heavy Metals						
Cadmium	Cattle		Kidney	9		
	Goats		Kidney	4		
	Horses		Kidney	11	10	
	Pigs		Kidney	11		
	Sheep		Kidney	10		
Lead	Cattle		Kidney	9		
	Goats		Kidney	4		
	Horses		Kidney	11		
	Pigs		Kidney	11		
	Sheep		Kidney	10		
	5 Sulphonamides	Calves	< 6	Kidney	55	
	Cattle		Kidney	64		
	Pigs		Kidney	732		
	Sheep		Kidney	106		
6 Antimicrobial Screen	Calves	< 6	Kidney	94		
	Cattle		Kidney	1,416		
	Goats		Kidney	10		
	Pigs		Kidney	819	1	
	Sheep		Kidney	3,262		
7 Annex IV						
Chloramphenicol	Calves	< 6	Kidney	21		
	Cattle		Feed	153		
	Cattle	< 24	Kidney	62		
	Pigs		Kidney	97		
	Sheep		Kidney	47		
Dimetridazole	Calves	< 6	Kidney	18		
	Cattle	< 24	Kidney	56		
	Horses		Kidney	10		
	Pigs		Feed	13		
	Pigs		Kidney	174		
	Sheep		Kidney	90		
Nitrofurans	Calves	< 6	Kidney	21		
	Cattle		Feed	136		
	Cattle		Kidney	63		
	Pigs		Feed	6		
	Pigs		Kidney	182		
	Sheep		Kidney	93	1	
8 Anthelmintics						
Avermectins	Cattle		Liver	226		
	Goats		Liver	7		
	Horses		Liver	11		
	Pigs		Liver	240		
	Sheep		Liver	354		
Benzimidazoles	Cattle		Liver	243		
	Horses		Liver	11		
	Pigs		Liver	253		
	Sheep		Liver	404	3	
	Levamisole	Cattle		Liver	98	
	Horses		Liver	10		
	Sheep		Liver	263		
9 Gestagens						
Altrenogest	Pigs		Kidney fat	123		
Gestagens	Cattle	< 24	Kidney fat	152		
	Cattle	< 24	Serum	80		

Type of Compound/Substance	Species	Age & Sex	Matrix	No. of Analyses	No. above Action Level
■ 10 NSAIDs	Sheep		Kidney fat	83	
	Cattle		Kidney	27	
	Horses		Blood	28	1
	Pigs		Kidney	33	
	Sheep		Kidney	75	
■ 11 Coccidiostats Ionophores	Calves	< 6	Liver	41	
	Pigs		Liver	9	1
■ 12 Mycotoxins	Sheep		Liver	316	
	Cattle		Liver	11	
	Pigs		Liver	9	
	Sheep		Liver	9	
■ 13 Dexamethazone/betamethazone	Cattle		Liver	45	
	Pigs		Liver	31	
	Sheep		Liver	12	
■ 14 Carbadox	Pigs		Liver	53	
	Calves	< 6	Liver	58	
■ 15 Sedatives	Pigs		Liver	183	
	Sheep		Liver	79	
■ 16 Thyrostats Carazolol	Pigs		Liver	183	
	Cattle	< 24	Serum	44	
	Cattle	< 24	Urine	120	
	Pigs		Urine	97	
	Sheep		Urine	57	
TOTAL				18,950	24

**NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN POULTRY MEAT
RESULTS OF TARGETED SAMPLING IN GREAT BRITAIN: 1 JANUARY 2003 – 5 JANUARY 2004**

Type of Compound/Substance	Species	Matrix	No. of Analyses	No. above Action Level	
■ 1 Hormones	Stilbenes	Broilers	Liver	136	
		Ducks	Liver	11	
		Hens	Liver	13	
		Turkeys	Liver	57	
	Trenbolone	Broilers	Liver	139	
		Ducks	Liver	10	
		Hens	Liver	12	
	Zeranol	Turkeys	Liver	56	
		Broilers	Liver	130	
		Ducks	Liver	7	
		Hens	Liver	7	
	■ 2 Pesticides Including PCBs	Carbamates	Turkeys	Liver	30
			Broilers	Liver	55
Ducks			Liver	10	
Hens			Liver	3	
Pyrethroids		Turkeys	Liver	24	
		Broilers	Liver	46	
		Ducks	Liver	9	
OC/PCBs		Hens	Liver	2	
		Turkeys	Liver	19	
		Broilers	Liver	212	
	Ducks	Liver	5		
■ 3 Beta-Agonist	Hens	Liver	4		
	Turkeys	Liver	33		
	Broilers	Feed	201		
	Broilers	Liver	342		
	Ducks	Feed	10		
	Ducks	Liver	15		
	Hens	Feed	10		
	Hens	Liver	16		
	Turkeys	Feed	49		
	Turkeys	Liver	75		
■ 4 Heavy Metal Cadmium	Broilers	Liver	25		
	Ducks	Liver	6		

Type of Compound\Substance	Species	Matrix	No. of Analyses	No. above Action Level	
Lead	Hens	Liver	12		
	Turkeys	Liver	22		
	Broilers	Liver	25		
	Ducks	Liver	6		
	Hens	Liver	12		
■ 5 Sulphonamides	Turkeys	Liver	22		
	Broilers	Kidney	71		
	Broilers	Muscle	179		
	Ducks	Kidney	4		
	Ducks	Muscle	9		
	Hens	Kidney	2		
	Hens	Muscle	8		
	Turkeys	Kidney	10		
	Turkeys	Muscle	26		
	■ 6 Antimicrobial Screen	Broilers	Kidney	264	1
Broilers		Muscle	711	1	
Ducks		Kidney	13		
Ducks		Muscle	31		
Geese		Muscle	1		
Guinea Fowl		Kidney	2		
Guinea Fowl		Muscle	1		
Hens		Kidney	11	1	
Hens		Muscle	30		
Turkeys		Kidney	79	1	
Turkeys		Muscle	196		
■ 7 Quinolones		Broilers	Kidney	92	
		Broilers	Muscle	251	1
	Ducks	Kidney	5		
	Ducks	Muscle	13		
	Geese	Muscle	3		
	Guinea Fowl	Kidney	1		
	Hens	Kidney	4		
	Hens	Muscle	12		
	Turkeys	Kidney	14		
	Turkeys	Muscle	34		
	■ 8 Annex IV	Chloramphenicol	Broilers	Liver	213
		Chloramphenicol	Broilers	Muscle	188
		Chloramphenicol	Ducks	Liver	10
		Chloramphenicol	Ducks	Muscle	7
Chloramphenicol		Hens	Liver	10	
Chloramphenicol		Hens	Muscle	12	
Chloramphenicol		Turkeys	Liver	48	
Chloramphenicol		Turkeys	Muscle	40	
Dimetridazole		Broilers	Feed	175	
		Broilers	Liver	640	
		Ducks	Feed	10	
		Ducks	Liver	25	
		Hens	Feed	8	
		Hens	Liver	27	
		Turkeys	Liver	122	
	Nitrofurans	Broilers	Feed	122	
Broilers		Muscle	668		
Ducks		Feed	4		
Hens		Feed	6		
Hens		Muscle	23		
Turkeys		Feed	77		
Turkeys		Muscle	131		
■ 9 Anthelmintics		Benzimidazoles	Broilers	Liver	122
	Benzimidazoles	Ducks	Liver	15	
	Benzimidazoles	Hens	Liver	12	
	Benzimidazoles	Turkeys	Liver	46	
	Levamisole	Broilers	Liver	121	
		Ducks	Liver	14	
		Hens	Liver	11	
		Turkeys	Liver	44	

Type of Compound\Substance	Species	Matrix	No. of Analyses	No. above Action Level
■ 10 Coccidiostats				
Ionophores	Broilers	Liver	261	2
	Hens	Feed	39	11
	Hens	Liver	7	
	Turkeys	Liver	71	
Nicarbazin	Broilers	Feed	22	1
	Broilers	Liver	250	46
	Hens	Feed	3	1
■ 11 Mycotoxins				
	Broilers	Liver	32	
	Ducks	Liver	5	
	Hens	Liver	3	
	Turkeys	Liver	13	
Total			7,636	66

**NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN FARMED FISH
RESULTS OF TARGETED SAMPLING IN GREAT BRITAIN: 1 JANUARY 2003 – 5 JANUARY 2004**

Type of Compound\Substance	Species	Age	Matrix	No. of Analyses	No. above Action Level
■ 1 Hormones					
Methyltestosterone	Salmon	Young	Muscle	19	
	Trout	Young	Muscle	5	
Nortestosterone	Salmon	Young	Muscle	33	
	Trout	Young	Muscle	2	
■ 2 Pesticides Including PCBs					
Pyrethroids	Salmon	Market	Muscle	42	
OC/PCBs	Salmon	Any	Muscle	75	
	Trout	Market	Muscle	8	
Organophosphorus	Salmon	Market	Muscle	36	
■ 3 Heavy Metals					
Cadmium	Salmon	Market	Muscle	5	
	Trout	Market	Muscle	5	
Lead	Salmon	Market	Muscle	5	
	Trout	Market	Muscle	5	
■ 4 Antimicrobial Screen					
	Salmon	Market	Muscle	122	
	Trout	Market	Muscle	6	
■ 5 Tetracyclines					
	Salmon	Market	Muscle	131	
	Trout	Market	Muscle	6	
■ 6 Quinolones					
	Salmon	Market	Muscle	110	
	Trout	Market	Muscle	7	
■ 7 Annex IV					
Chloramphenicol	Salmon		Muscle	58	
	Trout	Market	Muscle	4	
Dimetridazole	Salmon	Young	Muscle	154	
	Trout	Market	Muscle	12	
Nitrofurans	Salmon	Market	Muscle	33	
	Trout	Young	Muscle	3	
■ 8 Anthelmintics					
Benzimidazoles	Salmon	Market	Muscle	76	
	Trout	Market	Muscle	10	
Ivermectin	Salmon	Any	Muscle	169	
	Trout	Market	Muscle	7	
Levamisole	Salmon	Market	Muscle	32	
	Trout	Market	Muscle	9	
■ 9 Mycotoxins					
	Salmon	Market	Muscle	5	
	Trout	Market	Muscle	5	
■ 10 Malachite Green					
Malachite Green	Trout	Any	Muscle	87	1
Leuco Malachite Green	Trout	Any	Muscle	87	11
Malachite Green	Salmon	Young	Muscle	108	2
Leuco Malachite Green	Salmon	Young	Muscle	108	6
Total				1,389	20

**NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN EGGS
RESULTS OF TARGETED SAMPLING IN GREAT BRITAIN: 1 JANUARY 2003 – 5 JANUARY 2004**

Type of Compound/Substance	Species	Matrix	No. of Analyses	No. above Action Level
■ 1 Pesticides Including PCBs				
Pyrethroids	Free Range	Eggs	18	
OC/PCBs	Caged	Eggs	23	
	Free Range	Eggs	15	
	Perchery	Eggs	2	
■ 2 Antimicrobial Screen				
	Caged	Eggs	164	
	Free Range	Eggs	98	
	Perchery	Eggs	13	
■ 3 Tetracyclines				
	Caged	Eggs	52	
	Free Range	Eggs	32	
	Perchery	Eggs	5	
■ 4 Annex IV				
Chloramphenicol	Caged	Eggs	6	
	Free Range	Eggs	3	
	Perchery	Eggs	1	
Dimetridazole	Caged	Eggs	91	
	Free Range	Eggs	56	
	Perchery	Eggs	8	
Nitrofurans	Caged	Eggs	51	
	Free Range	Eggs	32	
	Perchery	Eggs	5	
■ 5 Anthelmintics				
Benzimidazoles	Free Range	Eggs	18	
■ 6 Coccidiostats				
Ionophores	Caged	Eggs	131	11
	Free Range	Eggs	79	10
	Perchery	Eggs	11	5
Nicarbazin	Caged	Eggs	131	
	Free Range	Eggs	78	
	Perchery	Eggs	10	
Total			1,133	26

**NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN MILK
RESULTS OF TARGETED SAMPLING IN GREAT BRITAIN: 1 JANUARY 2003 – 5 JANUARY 2004**

Type of Compound/Substance	Species	Matrix	No. of Analyses	No. above Action Level
■ 1 Pesticides Including PCBs				
Oc/Pcbs	Bovine	Milk	61	
Organophosphorus	Bovine	Milk	23	
■ 2 Heavy Metals				
Cadmium	Bovine	Milk	8	
Lead	Bovine	Milk	8	
■ 3 Sulphonamides				
	Bovine	Milk	161	
■ 4 Antimicrobial Screen				
	Bovine	Milk	570	
■ 5 Tetracyclines				
	Bovine	Milk	157	
■ 6 Quinolones				
	Bovine	Milk	246	
■ 7 Annex IV				
Chloramphenicol	Bovine	Milk	86	
Dimetridazole	Bovine	Milk	251	
■ 8 Anthelmintics				
Avermectins	Bovine	Milk	243	
Levamisole	Bovine	Milk	129	
■ 9 NSAIDs				
	Bovine	Milk	164	
■ 10 Mycotoxins				
	Bovine	Milk	150	1
Total			2,257	1

**NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN GAME
RESULTS OF TARGETED SAMPLING IN GREAT BRITAIN: 1 JANUARY 2003 – 5 JANUARY 2004**

Type of Compound\Substance	Species	Matrix	No. of Analyses	No. above Action Level	
■ 1 Hormones					
Stilbenes	Deer (Farm)	Liver	1		
Trenbolone	Deer (Farm)	Liver	2		
Zeranol	Deer (Farm)	Liver	2		
■ 2 Pesticides Including PCBs					
Carbamates	Deer (Farm)	Liver	3		
Pyrethroids	Deer (Farm)	Liver	3		
OC/PCBs	Deer (Farm)	Kidney Fat	6		
■ 3 Beta-Agonists					
	Deer (Farm)	Liver	2		
■ 4 Heavy Metals					
Cadmium	Deer (Farm)	Muscle	6		
	Deer (Wild)	Muscle	32		
	Partridge	Muscle	12		
	Pheasant	Muscle	12		
	Lead	Deer (Farm)	Muscle	6	
		Deer (Wild)	Muscle	32	
		Partridge	Muscle	12	1
		Pheasant	Muscle	12	
	■ 5 Antimicrobial Screen				
		Deer (Farm)	Kidney	17	
	Quail	Muscle	9		
■ 6 Annex IV					
Dimetridazole	Deer (Farm)	Liver	4		
	Partridge	Muscle	9		
	Pheasant	Muscle	7		
	Quail	Muscle	7		
■ 7 Anthelmintics					
Benzimidazoles	Quail	Muscle	11		
Ivermectin	Deer (Farm)	Liver	8		
Levamisole	Deer (Farm)	Liver	7		
■ 8 NSAIDs					
	Deer (Farm)	Liver	3		
■ 9 Coccidiostats					
Ionophores	Quail	Muscle	3		
Nicarbazin	Deer (Farm)	Liver	3		
Total			231	1	

■ RESULTS OF NON-STATUTORY SURVEILLANCE

The Non-statutory Veterinary Medicine Residue Surveillance Programme covers mainly imported produce and some home-produced foods that are not part of the National Surveillance Scheme (NSS). The programme can also carry out short surveys for areas of potential concern.

Non-Statutory Surveillance 2003

Since the start of the 2003 non-statutory surveillance programme the Central Science Laboratory has received 1,246 samples, which were collected between April and December and completed 5,056 analyses. Since the last report in MAVIS 48, 26 samples have been found to be above the Maximum Residue Limit/Action Level. Details of these positive samples are given below. The table of results give the rolling total for the year.

Nitrofurans

Seven samples of warm water prawns imported from Bangladesh (3), India (2), Indonesia (1) and Thailand/

Indonesia (1) contained residues of nitrofurans metabolites. The concentrations detected ranged from 1.2- 8.3µg/kg for the six samples containing the semicarbazide (SC) metabolite of nitrofurazone and 0.8µg/kg for the seventh sample containing the AMOZ metabolite of furaltadone.

Three samples of honey imported from Turkey (1), Spain (1), and Argentina (1) contained residues of the AOZ metabolite of furazolidone ranging between 0.3-1.4µg/kg.

The retailer and supplier of the Spanish honey sample has withdrawn the affected product from the market place and further investigations are underway in Spain and the UK. Information regarding the samples from Turkey and Argentina has been requested from the retailers concerned.

A sample of honey imported from Italy was found to contain residues of the AMOZ metabolite of furaltadone at a concentration of 1.4µg/kg.

Nitrofurans are prohibited for use in food producing species under Annex IV of EC Regulation 2377/90. Information for all these samples has been passed to the FSA for the issue of Rapid Alerts to the Commission. The CVO has asked officials in the countries of origin to investigate how these residues have occurred and to report what steps have been taken to ensure such substances are not used in future.

Streptomycin

Four samples of honey imported from Mexico and collected at a BIP were found to contain residues of streptomycin between 30 and 190µg/kg. Previous toxicological advice is that these residues would not be harmful to human health. The information has been passed to the FSA and Rapid Alerts have been issued. The CVO has asked officials in the country of origin to investigate these residues and report back their findings.

Sulphonamides

One sample of honey imported from Cyprus has been found under Antimicrobial screen testing to contain residues of sulphamethazine at 177µg/kg and 1,687µg/kg of sulphathiazine. The FSA has been notified and the CVO has written to the authorities in Cyprus notifying them of the results. Toxicological advice is that although the tolerance value of 100µg/kg has been exceeded, there is unlikely to be a significant risk to human health.

Malachite green/leucomalachite green

One sample of salmon imported from Chile was found to contain residues of leucomalachite green, a metabolite of malachite green, at a concentration of 2.6µg/kg. The sample was purchased from a retail outlet. Malachite green has never been authorised as a veterinary medicine in the EU and should not be present in imported farmed fish. This information was been passed to the FSA and a Rapid Alert has been issued. The Chilean authorities have responded to a letter sent to them by the CVO and investigations are underway.

Lasalocid

Seven samples of quail eggs purchased from retail outlets were found to contain residues of lasalocid at concentrations between 42 and 1,700µg/kg. The retailers and supplier concerned have been contacted and samples of feed for six of the samples have been analysed. The supplier of the seventh sample has contacted his feed supplier. The Royal Pharmaceutical Society of Great Britain RPS(GB) is investigating the cause of these residues at the mills concerned. Recent toxicological advice is that at these levels the residue is unlikely to be a significant risk to human health.

Nicarbazin

One sample of quail eggs purchased from a retail outlet was found to contain residues of nicarbazin (dinitrocarbanalide) at 220µg/kg. The retailer and supplier concerned have been contacted. The RPS(GB) is

investigating the cause of these residues at the feed mill concerned. Toxicological advice is that these residues do not pose a threat to human health.

Ivermectin

A sample of beef imported from Brazil has been found to contain residues of abarmectin at 11µg/kg (reporting level is 10µg/kg). The FSA has been notified and asked to issue a Rapid Alert and the CVO has written to the Brazilian authorities notifying them of this result.

SUMMARY OF PROGRESS SINCE THE LAST REPORT IN MAVIS 48

Nitrofurans

The Indian authorities have advised that they now have the ability the test samples by LC-MS-MS and are confident that the incidence of these residues will reduce in the future. The Ecuadorian authorities are liaising with the UK authorities.

In response to the CVO's letter informing the authorities in Bangladesh of the nine samples of prawns found to contain residues of semi-carbazide the officials in Bangladesh have responded that their method of analysis for the detection of nitrofurans is HPLC with UV detection limit of 0.1µg/kg. (MAVIS 48 Page 22).

Streptomycin

Following the FSA investigation into residues of streptomycin found in honey exported from Mexico, the importer has returned the two consignments concerned back to Mexico. (MAVIS 48 Page 22).

Malachite green/leucomalachite green

A meeting has taken place in London between representatives of the Chilean government, VMD and the FSA to discuss the residues of leucomalachite green found in the Chilean salmon. (MAVIS 48 Page 22).

**NON-STATUTORY SURVEILLANCE RESULTS
1 APRIL – DECEMBER 2003**

Matrix	Analyte	No. of samples analysed	MRL/Action Level where set µg/kg	No. of samples above Action Level
Imported farmed fish	Avermectins	133	100	
	Malachite green/ Leucomalachite green	198	Not set	6
	Quinolones	179	300 (oxolinic)	
Imported honey	Antimicrobial Screen	86	Not set	1
	Chloramphenicol	106	Not set	1
	Nitrofurans	103	Various	9
	Pyrethroids	62	Not set	
	Streptomycin	89	Not set	6
Imported raw beef	Avermectins	188	Not set	1
	β-agonists	301	Not set	
	Trenbolone	301	Not set	
	Zeranol	301	Not set	
Imported raw chicken	Antimicrobial Screen	267	Various	
	Clopidol	268	Not set	
	Fluoroquinolones	289	100 (total)	
	Nicarbazine	267	200	
	Nitrofurans	277	Not set	1
Quail eggs	Antimicrobial Screen	27	Not set	
	Dimetridazole/ronidazole	30	Not set	
	Lasalocid	30	Not set	12
	Nicarbazine	30	Not set	3
Warm water prawns	Antimicrobial Screen	307	Various	
	Chloramphenicol	307	Not set	
	Nitrofurans	297	Not set	23
	Quinolones	307	Not set	

**MARKETING AUTHORISATIONS ISSUED UNDER THE MARKETING AUTHORISATIONS FOR
VETERINARY MEDICINAL PRODUCTS REGULATIONS 1994 GAZETTED BETWEEN
26 AUGUST 2003 – 5 DECEMBER 2003**

Company	Vm Number	Product Name	Legal Category
Bio-Logix Laboratories Ltd	20118/4004	Bio-Tech's Anti-Flea and Anti-Tick Drops for Dogs	GSL
	20118/4006	Bio-Tech's Flea and Tick Drops for Dogs	GSL
	20118/4007	Bio-Tech's Flea Shampoo for Dogs	GSL
C-CORP LTD	19450/4002	Bimectin Pour-on for cattle	PML
Chanelle Pharmaceuticals Manufacturing Ltd	11990/4036	Provid 44% Paste	PML
Cross Vetpharm Group Ltd	12597/4041	Exodus	PML
	12597/4042	Maximec	PML
Eco Animal Health Ltd	13277/4015	Rapidex Pour-on for Cattle	PML
Intervet UK Ltd	01708/4492	Canigen KC	POM
	01708/4493	Canigen Lepto2	POM
	01708/4491	Canigen Pi	POM
	01708/4316	Metricure	POM
	01708/4322	Nobilis CAV P4	POM
Janssen-Cilag Ltd	00242/4043	Flubenol 50% Premix	PML
Merial Animal Health Ltd	08327/4206	Eqvalan Duo	PML
	08327/4208	Gallivac SE	POM
Norbrook Laboratories Limited	02000/4238	Combiclav Injection	POM
	02000/4240	Combiclav Lactating Cow Intramammary Suspension	POM
	02000/4239	Dynaclav Injection	POM
	02000/4220	Norocarp Tablets 20mg	POM
	02000/4221	Norocarp Tablets 50mg	POM
Novartis Animal Health UK Ltd	12501/4147	Atopica 100mg Capsule	POM
	12501/4144	Atopica 10mg Capsule	POM
	12501/4145	Atopica 25mg Capsule	POM
	12501/4146	Atopica 50mg Capsule	POM
	12501/4151	Johnson's 4Fleas 11.4mg Tablets for Cats and Kittens	GSL
	12501/4150	Johnson's 4Fleas 11.4mg, tablets for Small Dogs and Puppies	GSL
	12501/4149	Johnson's 4Fleas 57mg Tablets for Dogs	GSL
	12501/4010	Vet Kem Dog Spray	POM
	12501/4069	Fortekor 5 (for cats)	POM
	18343/4000	Pyceze	POM
Schering Plough Ltd	00201/4191	Scabivax Forte	POM
	00201/4182	Slice for Rainbow Trout	POM
	00201/4009	Finadyne Solution	POM
	00201/4036	Orbax 6.25mg Tablets	POM
	00201/4035	Orbax 25mg Tablets	POM
	00201/4037	Orbax 75mg Tablets	POM

The following tables list authorised variations which may affect the use of the product:

VARIATIONS APPROVED: 26 AUGUST 2003 – 5 DECEMBER 2003

Company	Product Name	Brief Details	
Ace Chemicals Ltd	Iodine Glycerine Teat Dip Rtu	Addition of Coloured Packs	
	Iodine Lanolin Glycerine Concentrate	Addition of Coloured Packs	
	Mastex	Addition of Coloured Packs	
	Teat Guard	Name of Product changed to Ruby Teatguard	
	Iodine Lanolin Glycerine Teat Dip Concentrate	Name of Product changed to Gold Teat Dip Concentrate	
Agrosolve Ltd	Postgard	Addition of Teat Spraying as a Method of Administration	
Aquaculture Vaccines Ltd	Aquavac FNM Plus Vaccine	Extension of Shelf Life	
Bayer (UK) Ltd	Baytril 2.5% Injection	MA/Holder Address changed to Bayer PLC, Animal Health Division, Bayer House, Strawbury Hill, Newbury, Berks RG1 1JA	
	Hyonate	" " " " "	
	Drontal Plus Tablets	" " " " "	
	Baytril Tablets 15mg	Product Name changed to Baytril Flavour Tablets and formula change	
	Baytril Tablets 150mg	Product Name changed to Baytril Flavour Tablets 150mg and formula change	
	Baytril Tablets 50mg	Product Name changed to Baytril Flavour Tablets 50mg and formula change	
	Drontal Cat Tablets	MA/Holder Address changed to Bayer PLC, Animal Health Division, Bayer House, Strawbury Hill, Newbury, Berks RG1 1JA	
	Baytril Piglet Doser	" " " " "	
	Binixin Injection	" " " " "	
	Droncit Spot On	" " " " "	
	Droncit Tablets	" " " " "	
	Baytril 10% Injection Solution	" " " " "	
	Baytril 10% Oral Solution	" " " " "	
	Bayer Ag	Advantage 40 For Cats	Address of Distributor changed to Bayer PLC, Animal Health Division, Bayer House, Strawbury Hill, Newbury, Berks RG1 1JA
		Advantage 40 For Dogs	" " " " "
Advantage 80 For Cats		" " " " "	
Advantage 100 For Dogs		" " " " "	
Advantage 400 For Dogs		" " " " "	
Advantage 250 For Dogs		" " " " "	
Bayer Plc	Top Drop for Large Cats	MA/Holder Address changed to Bayer PLC, Animal Health Division, Bayer House, Strawbury Hill, Newbury, Berks RG1 1JA	
	Top Drop for Large Dogs	" " " " "	
	Top Drop for Medium Dogs	" " " " "	
	Top Drop for Small Cats	" " " " "	
	Top Drop for Small Dogs	" " " " "	
	Baymec Pour-on for Cattle	" " " " "	
	Advantage for Small Cats and Small Dogs	" " " " "	
	Advantage for Small Cats, Small Dogs and Pet Rabbits	" " " " "	
	Drontal Plus XL Tablets	" " " " "	
	Bayer Dog Wormer Tablets	" " " " "	
	Baytril 5% Injection	" " " " "	
	Multi-Worm Tablets for dog	" " " " "	
	Fleegard 4 for Dogs	" " " " "	
	Bolfo Flea Spray	" " " " "	
	Quazitel 2.5% Suspension	" " " " "	
	Fleegard 8 for Cats	" " " " "	
	Fleegard 4 for Cats	" " " " "	
Fleegard 20 for Dogs	" " " " "		
Fleegard 10 for Dogs	" " " " "		

	Droncit Pills Droncit Spot On Equitape Horse Paste (Droncit Horse Paste 9%)	" " " " " Legal Category changed from POM to GSL MA/Holder Address changed to Bayer PLC, Animal Health Division, Bayer House, Strawbury Hill, Newbury, Berks RG1 1JA
	Droncit Injectable Rompun 2% Solution	" " " " " " " " " "
Boehringer Ingelheim Ltd	Vetmedin 1.25mg Capsules Vetmedin 2.5 mg capsules Vetmedin 5mg Capsules	Change of Storage Conditions Change of Storage Conditions Change of Storage Conditions
Chanelle Animal Health Ltd	Clinacin 75mg Tablets Clinacin 25mg Tablets Clinacin 150mg Tablets Chanaverm 7.5%	Shelf Life Extended Shelf Life Extended Shelf Life Extended Withdrawal Period (Increase)
Diverseylever Ltd	Deosan Teatcare Plus Deosan Super Ex-Cel Star Ready Dip Deosan Thixodip	MA/Holder Name changed to Johnson Diversy Ltd MA/Holder Name changed to Johnson Diversy Ltd MA/Holder Name changed to Johnson Diversy Ltd MA/Holder Name changed to Johnson Diversy Ltd
Eurovet Animal Health Bv	Sedaxylan	Additional Distributor
Fort Dodge Animal Health	Cydectin 1% Injectable Solution for Cattle Dysect Sheep Pour-On	Withdrawal Period Increased Additional Pack Size
Forum Products Ltd	Cefalexin Tablets 250mg Cefalexin Tablets 250mg	Product Name changed to Kefloril 250mg Tablets Additional Pack Size
Hypred Sa	Iodypro Propisderm Hexiprotect Ws Ioprotect Ws Tremplex	MA/Holder Name changed to Johnson Diversy Ltd MA/Holder Name changed to Johnson Diversy Ltd MA/Holder Name changed to Johnson Diversy Ltd MA/Holder Name changed to Johnson Diversy Ltd MA/Holder Name changed to Johnson Diversy Ltd
Intervet UK Ltd	Eryvac Dexadreson Nobilis Paramyxo P201 Canigen Dhppi Nobivac Lepto 2 Borgal 24% Solution	Additional Pack Type Shelf Life Extended Shelf Life Extended Change of Posology Change of Posology Shelf Life Extended
Johnson's Veterinary Products Ltd	Johnsons Insecticidal Flea And Tick Drops Johnson's Flea & Tick drops for Puppies and Small Dogs	Additional Safety Warnings Additional Safety Warnings
Merial Animal Health Ltd	Avinew Gallivac SE Progressis Hyoresp Pastobov	Change of MA/Holder, Address Meriel S.A.S (P), Laboratoire de Toulouse, 4 Chemin du Calquet 31057 Toulouse, Cedex, France "
Norbrook Laboratories Limited	Noroclox Dc Amoxycare La Injection Amoxycare La Injection Trimacare Bolus	Additional Pack Type Withdrawal Period Increased Withdrawal Period Increased Withdrawal Period Decreased
Novartis Animal Health UK Ltd	Robust Fasinex 5% Johnson's 4Fleas Tablets for Small Dogs and Puppies, Cats and Kittens Johnson's 4Fleas 11.4mg Tablets for Cats and Kittens, Small Dogs and Puppies Capstar 11.4mg Tablets Capstar 57mg Tablets	Shelf Life extended Additional Safety Warnings Removal of Indications Removal of Indications Legal category changed from POM to GSL Legal category changed from POM to GSL

Novartis Animal Vaccines Ltd	Pyceze	Additional Pack Size
Pfizer Ltd & Central Research	Stellamune Once	Change of Posology
Robinsons & Sons Ltd	Animalintex	MA/Holder Address & Name changed to Robinson Healthcare Ltd, Lawn Road Industrial Estate, Carlton-in-Lindrick, Worksop S81 9LB Animalintex Hoof Treatment " "
Schering Plough Ltd	Finadyne Solution Savlon Veterinary Concentrate Covexin 10	Withdrawal Period Increased Product Name changed to Savlon Veterinary Antiseptic Concentrate Shelf Life Extended
Sinclair Animal & Household Care Ltd	Friends Cat Flea Collar	Product Name changed to Canac Cat Flea Collar
The Bob Martin Co	Bob Martin Dog Spot On	User Safety Warnings
Vericore Ltd	Excis	MA/Holder changed to Novartis
Vetoquinol (UK) Ltd	Trimedoxine 4s Trimediazine Bmp Prilium 150mg Powder for Oral Solution	Withdrawal Period Decreased Withdrawal Period Decreased Shelf Life After Reconstitution Extended
Virbac De Portugal Laboratorios Lda	EQUIMAX	Additional Pack Size

**MARKETING AUTHORISATION AND VARIATIONS FOR
EU CENTRALLY AUTHORISED PRODUCTS
UNDER COUNCIL REGULATION (EEC) NO 2309/93
GAZETTED BETWEEN 26 AUGUST 2003 – 5 DECEMBER 2003**

Company	Product Name	Brief Details
Intervet International Bv/akzo (Holland)	Nobilis IB4 91	Removal of Contra-indications
Merial	Gallivac HVT IBD	MA Holder Name changed to Merial Animal Health Ltd
	PROTEQ Flu	" " " " " "
	PROTEQ Flu T	" " " " " "
Merial Animal Health Ltd	Eurifel FeLV	MA Holder Name changed to Merial Animal Health Ltd
	Neocolipor	" " " " " "
Novartis Animal Health Austria Ltd	Econor 0.5% Premix for medicated feed for Pigs	Indications modified

**EXPIRED MARKETING AUTHORISATIONS GAZETTED BETWEEN
26 AUGUST 2003 – 5 DECEMBER 2003**

Company	Vm Number	Product Name
Ancare (UK) Ltd	13158/4000 13158/4001	Oxfencare Oxfencare C
Bayer Plc	00010/4106	Armadosse Breakwormer
Bayer UK Ltd	00010/4067 00010/4048 00010/4058 00010/4047	Bayticol Scab And Tick Dip Bayverm Armadosse Bayverm Pellets 1.9% Bayverm Suspension 2.5%
Bimeda (UK) Ltd	03422/4001	Bimaclox Extra Dc

Bimeda Chemicals Ltd	02676/4161 02676/4157 02676/4162 02676/4128 02676/4124	Bimalong 25% Bimavite Plus Magnesium Sulphate 25% Tetroxy 10% DD Injection Tetroxy 5% Injection
Cross Vetpharm Group Ltd	12597/4000 12597/4006 12597/4005	Dipen Forte Osmonds Fendazole 10% Osmonds Fendazole 2.5%
Dales Pharmaceuticals Ltd	00123/4120 00123/4114	Battles Bloat Remedy Piperazine Citrate Tablets BP (vet) 500mg
Eli Lilly & Co Ltd	00006/4094 00006/4073 00006/4088	Brietal Sodium Veterinary Tylasul G100 Tylasul G50
Evans Vanodine International Plc	03940/4015	Agrimar Ready To Use Teat Dip
Hypred Sa	14153/4008	Teat Chlorhexidine Barrier
Intervet UK Ltd	01708/4224 01708/4390 01708/4423 01708/4271 01708/4465 01708/4209 01708/4442 01708/4248	Bovilis Ibr P13 Live Coliovac Dimazon 40mg Tablets Ionalyte Levacur 7.5% SC Nobivac Puppy Dp Panacur Pet Paste Sesoral
Ivex Pharmaceuticals	05271/4008 05271/4009	Calciflex 20 Calciflex 40
Lloyd Europe Ltd	15914/4000	Anased 10%
Mars UK Ltd/ta Thomas's Europe	05707/4000	Pedigree Care Anti-Flea And Anti-Tick Drops
Merial Animal Health Ltd	08327/4185	Rycomec Injection For Sheep
Norbrook Laboratories Limited	02000/4149 02000/4165	Econopen Injection Nemanil
Novartis Animal Health UK Ltd	12501/4055 12501/4012	Hartz Health Measures Rid Worm for Dogs and Puppies Program Tablets 23.1mg
Pfizer Ltd	00057/4204	Clamoxyl Oral Multidoser
Schering Plough Ltd	00201/4095 00201/4051 00201/4052 00201/4112 00201/4005 00201/4017 00201/4016 00201/4101 00201/4110 00201/4091 00201/4102 00201/4063 00201/4057	Autoworm Mark II Pulse Release Cattle Wormer Betsolan Cream Betsolan Eye And Ear Drops Cepnavin Eye Ointment Finabiotic Finadyne Tablets 20mg Finadyne Tablets 5mg Tribrissen Bolus Grenade 2% Pour On Systemex Paste Horse Wormer Tribrissen Oral Suspension Tribrissen Piglet Suspension Vetsovate Cream
Thomas Pettifer & Co Ltd	14031/4004	Green Oils
Thomass Europe	06804/4005	Advance Anti-Flea and Anti-Tick Drops
Vericore Ltd	17381/4000	Micrapor
Vetoquinol (UK) Ltd	08007/4100 08007/4071 08007/4069 08007/4072 08007/4043	Doxyseptin 300 Flexadin 5% Premix Lignadrin Penillin 300 Long Acting Sulfoxine 333